Science Centre North Rhine-Westphalia
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Wuppertal Institute for Climate, Environment and Energy

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Intellectual Property Rights and Biological Resources

An Overview of Key Issues and Current Debates

Wuppertal Papers

No. 151 · February 2005
ISSN 0949-5266

Publisher:

Wuppertal Institute
for Climate, Environment and Energy

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Abstract

This paper aims to provide a comprehensive background and overview of key issues, debates and positions related to the international regulation and application of intellectual property rights over biological resources, including biotechnology, and the use and protection of the traditional knowledge of indigenous and local communities. It explores the linkages among biological diversity, rural livelihoods, biotechnology developments and intellectual property with specific view on the relationship between access to biological and genetic resources, agriculture systems, food security, and increased poverty levels around the world.

The paper starts by outlining the background and evolution of intellectual property rights. It then provides two case studies on how intellectual property rights affect biodiversity and traditional knowledge. In the main part, the paper indulges on the international governance of biodiversity and intellecutal property rights, especially focussing on the Convention of Biological Diversity (CBD), the World Intellecutal Property Organization (WIPO), and the World Trade Organization with its Agreement on Trade-Related Aspects of Intellecutal Property Rights (TRIPS). However it also sheds light on the increasing impacts of bilateral agreements that govern intellectual property rights in conjunction with the plurilateral International Union for the Protection of New Varieties of Plants (UPOV), and it analyses their relationship with the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the CBD. The paper finishes by sketching out ideas for a way forward.

1. Introduction: Setting the scene

This paper* aims to provide a comprehensive background and overview of key issues, debates and positions related to the international regulation and application of intellectual property rights (IPRs) over biological resources, including biotechnology, and the use and protection of the traditional knowledge of indigenous and local communities. The linkages among biological diversity, rural livelihoods, biotechnology developments and intellectual property have been increasingly explored and analysed in recent years. The application of IPRs to plant varieties and the role of biotechnology have particularly important implications given the relationship between access to biological and genetic resources, agriculture systems, food security, and increased poverty levels around the world.

There is a growing interest on the potential commercial uses of biodiversity, which is driving many of the policy and legislative developments in this area, such as the sharing of benefits, the role of traditional knowledge-holders, and the role and responsibilities of countries that provide and use these resources and knowledge. A 1999 study provided estimates of the size of global markets for uses of genetic resources in the pharmaceutical, seed, cosmetic, horticultural and botanical medicine industries, with figures ranging from US$20 billion a year in the horticultural sector, to US$300 billion a year in the case of pharmaceuticals[1]. The commercial seed market has been estimated at US$30 billion a year and is fast growing due to increasing food demands[2]. However, it should be added that the non-commercial cultural and spiritual values of biodiversity for rural and indigenous communities all over the world are more difficult to calculate in monetary terms but also more important for them and their own survival[3].

Since the early 1990s, an interesting parallel process has taken place: on the one hand, international law and policy have shifted from considering biological genetic resources as common heritage of humankind — and therefore free for all — to giving States sovereignty and control over these resources. In addition, this situation has been further affected by the increased promotion of private ownership and the use of IPRs over plant and crop varieties. Another factor to be considered is that most developing countries did not have IPR regulations before they joined the World Trade Organisation (WTO) in 1995 and so they are tackling the implementation of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) while they are also addressing the application of other relevant regimes such as the Convention on Biological Diversity (CBD) and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

* The author would like to thank Shikha Bhakoo for her research assistance in the preparation of this paper.

1 ten Kate K and Laird S, The commercial use of biodiversity, 1999, Earthscan, London.

2 Dutfield G, Intellectual Property Rights, Trade and Biodiversity, 2000, Earthscan, London

3 Id.

Together with the ongoing emphasis on genetic resources and the use of biotechnology to develop new varieties and products, there is growing international interest on the potential applications of the knowledge and know-how that indigenous peoples and rural communities have developed and applied to natural resources over generations. Concerns have been raised as to the ways in which traditional knowledge, innovations and practices are being accessed and used by non-indigenous individuals and by public and private researchers and companies in both industrialised and developing countries. Different ways and options to regulate access to genetic resources, the potential uses of such genetic material, and the fair and equitable sharing of the benefits that may be derived from genetic resources and associated traditional knowledge, are being explored by a number of international organisations in multiple fora. In this context, positions are shifting as countries further their understanding of possible policy and regulatory options and mechanisms to protect the rights of traditional knowledge-holders at the national and international level, as well as the implications of those options on other policy areas, such as research, trade or agriculture.

Two major groups of civil society are closely linked to the shaping of national positions and policy, as well as public opinion, on these issues, although with a different degree of influence : (i) industry and the private sector, and (ii) grass-roots organisations, and environmental and development Non-Governmental Organisations (NGOs). They operate at different levels and in very different ways, as the motivation is clearly distinct. While industry s lobbying takes place mostly in closed circles, NGOs campaign on these issues through the use of the media in informing the general public to raise public awareness of these highly complex new issues: biotechnology, intellectual property rights, bioprospecting, trade, and their impact on the environment and rural livelihoods. NGOs portray through the media specific experiences and examples of the shortcomings of the current international legal and policy framework such as patents granted in the US over the neem tree, basmati rice, and the Andean root crop maca .

At the heart of these issues lies the complexity of the international system governing biodiversity, access to genetic resources, the protection of traditional knowledge and the use of intellectual property rights. The web of international treaties and regional conventions governing biodiversity and IPRs, and the increasing number of bilateral trade agreements between industrialised nations and developing countries requiring the latter to accept stricter IPR standards than they are obliged to under global rules, are all contributing to a rapidly changing and highly uncertain policy environment, which is affecting the world s rapidly dwindling biological diversity. This situation is not helped by the fact that a number of international agencies and institutions overlap on these issues and are pursuing different agendas and priorities with varying levels of co-ordination with the rest. Lack of agreement among the countries member of such agencies on which institution should take the lead on which issue also marks the current state of affairs, which is resulting in a slow pace of progress towards finding the solutions that are urgently needed.

The extent to which developing countries can influence the outcomes of the international IPR debate has been analysed by a number of academics and activists, with the overall conclusion that they have comparatively little influence [4]. The main reason for this lack of influence over the years, which can be tested on the outcomes of international debates on IPR issues, has been found to lie on the continued use of webs of coercion by the US and EU, both of which remain united on the need for strong global standards of intellectual property [5]. The same author evaluated the TRIPS negotiations in accordance with a theory of democratic property rights , arguing that efficient property rights are more likely to emerge if three conditions are met[6]: (i) all relevant interests have to be represented in the negotiating process (the condition of representation); (ii) all those involved in the negotiation must have full information about the consequences of various possible outcomes (the condition of full information); and (iii) one party must not coerce the others (the condition of non-domination). Drahos concluded that the negotiations of the TRIPS Agreement did not meet these conditions of democratic bargaining.

A central question is whether the international acceptance and expansion of common standards of patent protection through international treaties, which were developed to meet the conditions and needs of advanced industrialised countries, may have the effect of undermining biodiversity, traditional knowledge-systems, and the food security of communities in developing countries. Globalisation has emphasised the linkages and conflicts between international trade rules, domestic priorities, standards of IPR protection, and resource needs, which are resulting in a fast expanding gap between industrialised and developing countries, as well as in growing differences and inequalities within those countries. As stated in its title, this paper aims to provide an overview of those key issues and current debates regarding the nature of and linkages between IPRs and biodiversity, with the objective of shedding some light over the impact of policy developments and country positions on the future life of the planet.

4 Drahos P, Developing Countries and International Intellectual Property Standard-setting, Study Paper 8, 2002, commissioned by the UK Commission on Intellectual Property Rights.

5 Id.

6 Id.

2. The evolution of intellectual property rights

2.1 Background

Patents and other intellectual property rights (IPRs) are awarded to individuals or organisations mainly for inventions and creative works, giving the creator/inventor the incentive of a right to prevent others from unauthorised use for a limited period of usually 20 years. The basis of IPRs is to provide incentives to promote and reward technical and technological innovation and artistic developments. Patent owners receive exclusive rights for a fixed period of time during which they control the commercial use of their invention.

Patent protection has its origins in industrialised countries, and more specifically in Europe, where early types of patents can be traced back to the 14th century. However, patents were regulated in the late 18th century and during the 19th century in the US and some European countries with the objective of encouraging the import and local adaptation of technologies that had been developed and tested elsewhere. Many European countries formalised and enforced IPRs gradually, as they shifted from being net users to net producers of intellectual property, with countries such as France, Germany and Switzerland only completing what is now considered standard IPR protection in the 1960s and 1970s. It is worth recalling that before the adoption of the Paris Convention for the Protection of Industrial Property in 1883, countries had had total discretion to adopt national IPR regimes in line with their own circumstances and needs. In addition, the 1883 Paris Convention allowed countries to exclude areas of technology from patenting and to determine the duration of patents themselves. This level of flexibility which was used by industrialised countries to expand and strengthen their industrial competitiveness, as they were developing , is currently being denied to developing countries.

The implications of this evolution are two-fold: (i) tight and uniform IPRs were not the only way technologies were transferred between industrial countries, and (ii) each country developed its own way of introducing IPRs at its own pace, which highlights the importance for developing countries to create their own IPR strategies, even within the multilateral regime[7]. Not surprisingly, those countries that first developed IPRs, and which strengthened their regimes as their industries needed to protect their investments, were instrumental in placing IPRs at the core of the international trade agenda. This was achieved by promoting a specific agreement to ensure minimum IPR standards as part of the package deal that countries had to accept to become members of the World Trade Organisation (WTO) in the mid-1990s.

7 UNDP, 2001 Human Development Report, Chapter 5.

The 2001 Human Development Report[8] reminds us that Article 27 of the 1948 Universal Declaration of Human Rights recognises everyone s right „to the protection of the moral and material interests resulting from any scientific, literary or artistic production" of which they are the author, as well as „the right to share in scientific advancement and its benefits". The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) also calls for a balance between the promotion of technological innovation and the transfer and dissemination of technology (emphasis added). The UNDP report exposes two problems with the global IPR regime which represent major obstacles for progress in human development. One of them is that IPRs can go too far and hamper innovation, rather than encourage it, and unfairly distribute the ownership of knowledge. The second one signals problems to achieve a fair implementation of the TRIPS Agreement. The UNDP report considers that these two trends „hamper innovation and shift traditional knowledge into private hands".

The conflict and controversy that surrounded the negotiations of the TRIPS Agreement have continued regarding its implementation and review in recent years. International discussions on the "correct" or most appropriate international system of IPRs, and the merits of global harmonisation, have been largely related to the desirability of achieving such uniformity at a strong and strict, rather than flexible, standard of IPR enforcement[9]. Harmonised standards result in the need to align domestic and international laws, the latter having been based to a very large extent on the domestic legal frameworks of one or several similar countries. International rules on IPRs create the obligation to adopt legal concepts and frameworks based on western cultures and values. International rules, shaped closely in accordance with the needs of industrialised nations to protect the interests and investments of their industries, are forced on societies with different priorities and needs, in the name of globalisation.

Since 1980, when the US was the first country to accept a patent on a living organism[10] (and more specifically: a genetically modified micro-organism)[11], such patents have increased in industrialised countries. That patent granted in 1980 started a growing trend to issue patents not only for inventions for also for discoveries of information already existing in the natural world, as it has been the case of the genetic sequencing of living organisms[12]. One of the main consequences of these developments has been the commoditisation and privatisation of biodiversity, focusing exclusively on the commercial value of genetic

8 Id.

9 David P A, The Evolution of Intellectual Property Institutions and the Panda s Thumb, paper presented at the Meetings of the International Economic Association, Moscow, August 1992.

10 Decision of the US Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303 (1980).

11 In 1985, the US Patent and Trademark Office (PTO) ruled that plants could qualify under the utility patent laws. In 1987, the US PTO ruled that animals are also patentable. As a result of these decisions, virtually all living organisms in the US, including human genetic material, became patentable subject matter.

12 Laird S A (ed.), Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice, WWF, 2002.

resources to the detriment of non-monetary values. It comes as no surprise that precisely the countries behind the establishment of global rules and standards for IPR protection have been those where the main corporations, investing in research and development in search of new commercial products, are located.

As it has been explained above, intellectual property law, which includes patents as well as trade marks, industrial designs and geographic indications, arose from the needs of inventors during the industrial revolution, while the owners and keepers of biological genetic resources and traditional knowledge have different customs, institutions and needs which are not adequately reflected in the current global framework. In no unclear terms, the UN has found that despite industrialised countries commitments included in the TRIPS Agreement, „they have taken no real steps to share their technology in the interests of reducing poverty“[13].

The evolution of IPR regimes in industrialised countries, led by the US and Europe, has been characterised by the widening of the subject matter subject to IPR protection (e.g. the extension of patent protection to cover life-forms, cell lines and DNA sequences); the creation of new rights, such as plant breeders rights; and the progressive standardisation of the basic features of IPRs (such as 20-year protection terms; prior art searches; and requirement to examine applications for their novelty, inventive step and industrial application, among others). However, the situation was far from homogeneous, with countries such as France, Belgium and Italy granting patents on the basis of registration until the 1960s, and many European countries having lifted the bar to the patentability of pharmaceutical products only in the 1960s and 1970s[14]. At the same time, a few developing countries were moving in the opposite direction on the same issues: Brasil and India adopted laws to exclude pharmaceuticals from patentability in the late 1960s and early 1970s[15].

2.2 IPRs and development

The contribution of IPR regimes to access to technologies by developing countries, a crucial factor for their development, and the role of IPR protection in reducing poverty and promoting progress in developing countries, is being increasingly studied. However, lack of information and data regarding developing countries have resulted in emerging conclusions and trends pointing towards conflicting messages on the relationship between IPRs and development. A 2001 report commissioned by the World Intellectual Property Organisation (WIPO) states that, although studies have generally shown a positive connection between IPRs and both foreign direct investment (FDI) and imports, results are not

13 UNDP, 2003 Human Development Report, Chapter 8, Oxford University Press, 2003.

14 Dutfield G, Literature survey on intellectual property rights and sustainable human development, February 2002. See at http://www.iprsonline.org/unctadictsd/docs/bioblipr.pdf

15 Id.

consistent for all sectors for reasons which are not entirely explained [16]. The paper adds that there is compelling evidence that stronger IPRs do indeed provide some domestic benefits for developing nations , a factor which the author considers particularly relevant in the WTO era when governments have fewer policy options available .

A different conclusion was however reached by the UK Commission on Intellectual Property Rights, an independent body set up in May 2001 by the British government and which released its final report in September 2002. The Commission s report set out a number of recommendations on IPRs and their links to efforts to reduce poverty in developing countries. Some of the Commission s conclusions on the effects of IPRs on development were that[17]:

- There is some evidence that trade flows into developing countries are influenced by the strength of IPR protection, particularly for industries that are IPR sensitive such as chemicals and pharmaceuticals, but the evidence is far from clear;
- The evidence that foreign investment is positively associated with IPR protection in most developing countries is lacking; and
- Most of the evidence concerning the role of IPRs in trade and investment relates to those developing countries that are more technologically advanced. For other developing countries, any beneficial trade and investment effects are unlikely to outweigh the costs, at least in the short and medium term.

The UK Commission on IPRs and other research and discussion fora[18] on intellectual property policy issues and their impact on development have identified IPRs as a tool to promote innovation and contribute to increasing developing countries competitiveness, rather than as an end in themselves. IPR policies should be linked to and respond to the national circumstances and development strategies of developing countries, and not be forced upon them unconnected to their development needs and priorities.

2.3 Patent requirements

The TRIPS Agreement entered into force in 1995 with the establishment of the World Trade Organization (WTO) and is the most relevant WTO agreement in relation to biodiversity, including plant varieties. TRIPS was one of the most controversial agreements

16 Lesser W, The effects of TRIPS-mandated intellectual property rights on economic activities in developing countries, April 2001, at http://www.wipo.int/about-ip/en/studies/pdf/ssa_lesser_TRIPS.pdf

17 Integrating Intellectual Property Rights and Development Policy, UK Commission on Intellectual Property Rights, London, September 2002.

18 ICTSD-UNCTAD Dialogue on Development and Intellectual Property, 18-21 September 2003, Bellagio, Italy. See meeting report at http://www.iprsonline.org/unctadictsd/bellagio/docs/Bellagio2_Report.pdf

of the WTO package and the compromise reached included an extended deadline for developing countries to implement it, as they were granted five extra years to comply (i.e. by January 2000), while least developed countries (LDCs) have until January 2006[19]. The requirements of the TRIPS Agreement are considered the minimum level of global IPR protection, and so countries need to implement those minimum IPR standards. The harmonised global standards established by TRIPS represent significant changes for many countries, especially for developing countries. Most of them did not have any legislation on IPRs prior to joining the WTO, as this was not considered a priority, while the link between IPRs and progress in development levels has yet to be proven.

The TRIPS Agreement requires all WTO members to provide minimum standards of protection for a wide range of IPRs, including patents, copyright, trademarks, and geographical indications, and it incorporates provisions from many existing international agreements on IPRs which are administered by WIPO (see section 4.2). Although the details and interpretation vary from country to country, there are three main requirements for patentability, established by the TRIPS Agreement. Patents must be available for: (i) any invention, whether products or processes, (ii) in all fields of technology, and (iii) provided that they are new, involve an inventive step and are capable of industrial application (emphasis added). The TRIPS Agreement adds a note further explaining that for the purposes of such provision, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful", respectively, which mirror their US interpretation. The TRIPS Agreement allows WTO members to establish exceptions from the general obligation of patentability for "any inventions". The exceptions to this rule are included in Article 27(3)(b) and concern plants and animals. However, countries are obliged to protect micro-organisms and certain biotechnological processes through patents, and therefore no exceptions are permitted for them.

Article 27(3)(b) is one of the most controversial provisions of the TRIPS Agreement and a good example of an international compromise reached between opposite positions, which is why some countries consider that it goes too far in its minimum rules on patenting, while others argue that it does not go far enough. Although this Article allows a certain degree of flexibility to determine whether patents on animals or plants can be granted by WTO members, there is no room for discretion in the case of micro-organisms, which must be subject to patenting in any case[20]. Many developing countries have expressed

19 The Doha Ministerial Declaration on the TRIPS Agreement and Public Health allowed 10 extra years for LDCs implementation of the agreement in respect of pharmaceutical products (i.e. until 1 January 2016).WTO document WT/MIN(01)/DEC/2, of 20 November 2001.

20 See UNCTAD-ICTSD Resource Book on TRIPS and Development. An Authoritative and Practical Guide to the TRIPS Agreement ,2003.

(NB. the exceptions to patentability of Article 27.2 of the TRIPS Agreement also apply: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law").

concern about these measures in light of some landmark cases where developed countries have granted patents based on genetic resources or traditional knowledge from developing countries. Article 27(3)(b) has also generated a lot of debate as it addresses patents related to the use of biotechnology on biological materials.

An important element in the ongoing controversy regarding this provision is the mandate to review subparagraph 27(3)(b) four years after the entry into force of WTO (i.e. by 1999). There has been no progress on this issue so far, as developed countries hold the view that a "review of implementation" should be conducted, while developing countries argue that the "review" must include the revision of the provision itself[21].

In the context of plant genetic resources, it must be clarified that when plants have been subject to technical or technological interventions for the production of new plant varieties, they are subject to a different regime and therefore not covered by the patentability exception. Plant varieties are considered new organisms, different from wild plants as found in nature, and require protection through patents or sui generis (meaning of its own kind or special) regimes. This different treatment of plant varieties in the TRIPS Agreement reflected the lack of consensus among negotiating countries, mainly between the US and Europe[22], although since then their standards are becoming closer. While the 1973 European Patent Convention states that plant and animals are not patentable[23], there has been differing interpretations of this provision which led to the adoption in 1998 of an EU Directive[24] to standardise patents in EU countries. The directive does not totally exempt plant varieties from patentability, as biological material isolated from its natural environment or produced by a technical process "may be the subject of an invention even if it previously occurred in nature"[25], a provision which has been criticised by NGOs and by some EU countries themselves.

A major impact of the increased used of biotechnology on seed and plant production, whose results are subject to patent or patent-like rights such as plant breeders rights, has been the promotion of the control of the private sector over crops and agricultural practices, making farmers liable for royalty payments and changing their traditional practices by restricting their use and exchange of seeds.

With regard to globalisation and food safety, the introduction and strengthening of IPRs in agriculture raises concerns that over-patentability in the agro-biotechnology industry may have the potential to stifle innovation rather than promote it, both in the public and

21 ICTSD-UNCTAD Resource Book on TRIPS and Development, Part II: Substantive Obligations. See at http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm

22 Stewart T (ed.), The GATT Uruguay Round. A Negotiating History (1986-1992): Introduction and Overview, Kluwer Law, 1993.

23 Article 53 of the 1973 European Patent Convention.

24 Article 4(1)(a) of Directive 98/44/EC on the legal protection of biotechnological inventions (Official Journal L 213, 1998).

25 Id, Article 3(2).

private sectors[26]. In addition, the implications of IPR policies on research priorities and funding points towards a more likely focus on the development of commercially sound products rather than on the needs of individuals and communities living in poverty[27]. The private sector is a major player in biotechnology research globally. The biggest life science companies have a reported investment of some US$2.6 billion in agricultural research and development in 1998, but only a small share of this amount is directed at developing countries. Most private sector investment in biotechnology R&D takes place through: (i) direct investment by global life science companies; (ii) acquisition by these companies of seed companies in developing countries, and (iii) through alliances between global and local companies[28].

Finally, it is interesting to consider some of the recommendations by the UK Commission on IPRs on the patent system, addressed to developing countries from the perspective of their development needs and options[29]:

- Exclude from patentability plants and animals and adopt a restrictive definition of micro-organisms;
- Avoid using the patent system to protect plant varieties and where possible, genetic material;
- Provide for international exhaustion of patent rights;
- Apply strict standards of novelty, inventive step and industrial application or utility (consider higher standards than currently applied in developed countries);
- Make use of strict patentability and disclosure requirements to prevent unduly broad claims in patent applications;
- Provide means to prevent the granting or enforcement of patents comprising biological material or associated traditional knowledge obtained in contravention of access legislation or the provisions of the CBD.

In conclusion, the international patent system is based on the value system of Western countries, which provides for exclusive individual rights as an incentive for industrial innovation. Developed countries designed their IPR regimes in accordance with their own needs and circumstances and then placed made their tailor-made regimes the global IPR standard for all countries. The Western values that IPRs represent often clash with those of developing countries. The privatisation and commodification of life and biodiversity through patents on living matter, which in some countries extend to human genetic material, is alien to many countries and communities in the developing world. However, they cannot opt out from the TRIPS agreement as the WTO was negotiated as a package deal .

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26 Cullet P, Food Security and Intellectual Property Rights in Developing Countries, IELRC Working Paper 2003-3.

27 Id.

28 Byerlee D and Fischer K, Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries, World Development Vol. 30 Issue 6, 2002.

29 See n.17.

3. IPRs, biodiversity and traditional knowledge

Concerns have been raised by developing countries and civil society about the impacts of IPRs on biodiversity, traditional knowledge systems and farmers rights. Patents and plant breeders rights over plant varieties require these to be genetically uniform, which favours the commercial production of seeds at a global scale rather than locally adapted varieties. The cultivation of uniform varieties is both linked to the loss of agro-biodiversity and to the increase of genetic erosion, making crops more vulnerable to diseases. IPRs play an important role in this equation as they provide incentives to develop seeds that can be used in a large market and which derive profits through IPRs. Some of the main effects of IPRs on biodiversity have been identified as[30]: decreased crop diversity; decreased spatial genetic diversity; increased temporal genetic diversity, and increased use of external inputs.

The FAO has estimated that 1.2 billion people live in poverty across the developing world[31]. Although the relative importance of rural poverty varies from country to country, more than 70 percent of total poverty in developing countries is found in rural areas, where farming is the main basis of local livelihoods. The impacts of IPR laws in developing countries are potentially very negative for small farmers, with 1.4 billion people depending on saved seed while patents take away this traditional practice of farmers[32], also considered a so-called farmers privilege . Patents can also make seeds more expensive for small farmers due to royalty payments, restrictive contracts and increased commercialisation, which compromise farmers rights to save, grow, exchange and sell seed. Farmers indigenous variety of seeds not only ensures biodiversity but also the livelihood of poor farmers. Genetic diversity in agriculture enables poor farmers and breeders to select varieties of plants and animal breeds that are best adapted to changing environmental, economic and social pressures[33].

According to ActionAid[34], six corporations (Aventis, Dow, Du Pont, Mitsui, Monsanto and Syngenta) are buying up local seed markets in the developing world and controlling global markets, jointly holding 98 per cent of the global market for patented genetically modified (GM) crops, 70 per cent of the global pesticide market, and 30 per cent of the global seed market. The same study reported that those six major agrochemical corporations hold the vast majority of the 918 patents on rice, maize, wheat, soybean and sorghum, with 633 patents, or nearly 69 per cent, on the staples that are vital for the poor, a

30 UNCTAD-ICTSD, Intellectual Property Rights: Implications for Development, Policy Discussion Paper, August 2003.

31 Dixon J, Gulliver A and Gibbon D, Farming Systems and Poverty: Improving farmers livelihoods in a changing world, FAO/World Bank, 2001.

32 Madeley J, Crops and robbers, ActionAid, October 2001.

33 Lewis J (ed.), TRIPS ON TRIAL: The Impact of WTO s Patent Regime on the World s Farmers, the Poor and Developing Countries, Action Aid, Berne Declaration, IATP, Misereor, September 2001.

34 See n. 32.

figure which rises to 76 per cent in the case of soybean. Patents are considered to promote the consolidation of global seed and agro-chemical businesses, concentrating power over seeds and seed choices in very few hands[35].

The private sector has stressed[36] that the gap between access to genetic resources and traditional knowledge and the release of a product is a long one, involving considerable investment to develop the original resources into suitable products. In addition, not all trials result in commercial successes, which may in turn affect the flow of benefits to the source country or the communities involved.

In the area of traditional knowledge, the World Health Organization (WHO) has estimated the global market for traditional therapies as reaching US$ 60 billion a year, and rapidly growing[37]. The WHO has also identified the need to establish policies on the protection of indigenous knowledge given the risks raised by the impacts that further commercialisation and unregulated use of traditional plants and medicines may have for those who rely on these materials as their primary or even only source of health care.

In addition, the UN Sub-Commission for the Protection and Promotion of Human Rights unanimously adopted a resolution on "Intellectual Property Rights and Human Rights" in August 2000, stating that the TRIPS Agreement could infringe the rights of the world s poorest to access seeds and pharmaceuticals[38]. The resolution recognises that there is a conflict between the private interests of IPR holders and the social or public concerns embodied in international human rights law, and requested governments to "integrate into their national and local legislations and policies, provisions, in accordance with international human rights obligations and principles, that protect the social function of intellectual property"[39].

A 2001 study by the FAO and the World Bank[40] outlined key strategic priorities for action to accelerate the process of decline in hunger and poverty in developing regions, with a focus on creating dynamic rural communities based on prosperous farming. The paper concluded with a list of proposed actions aimed at contributing towards achieving the global target of halving hunger and poverty by 2015. The central message of this FAO/ World Bank study is the great potential that improvement of smallholder farming systems has for reducing hunger and poverty, since half of the population of developing regions, and a majority of the hungry and the poor, are farmers and their families. However, it is

35 Tripathi R, Food patenting — A threat to food security, ActionAid, 2001.

36 Bennet A (Executive Director of the Syngenta Foundation for Sustainable Agriculture), Saving genes through improved access and benefit sharing, Symposium on Food Security and Biodiversity, 16 October 2003, Basel, Switzerland. See at http://www.syngentafoundation.com/pdf/andrew_bennett_genes_benefit_sharing.pdf

37 World Health Organisation, Press release WHO/38, of 16 May 2002.

38 UN Resolution E/CN.4/Sub.2/2000/L.20.

39 Id.

40 See n.31.

noticeable that such a study did not include any consideration or reference to the role and influence of IPR systems, neither as part of the global challenges faced nor in the list of ways forward.

The fact that patents on genetic resources do not recognise the rights of local communities over their traditional knowledge has been raised by numerous developing countries and NGOs since the adoption of the TRIPS Agreement. Traditional knowledge associated to biodiversity is often instrumental in determining the properties or uses of resources that form the basis of the discovery or invention subject to patent. While fewer than 1 per cent of flowering plants have been thoroughly investigated by modern science, traditional knowledge of their biology and use is great by comparison[41]. However, traditional knowledge systems, including community institutions for conservation, exchange and improvement of biological diversity, have also contributed to the erosion of traditional knowledge itself. It has been stressed as ironic that many countries complain about the unfair way in which traditional knowledge and genetic resources are treated at the international level while very few take measures to stop a similar exploitation in domestic markets[42].

Granting private property rights over the intellectual developments of many previous generations of farmers raises serious questions in respect to prior art , and can also viewed as a form of intellectual property theft — the so called bio-piracy [43], also defined as ”the illegal appropriation of life — micro-organisms, plants, and animals — and the traditional cultural knowledge that accompanies it”[44]. Meeting the patent requirement of novelty in relation to traditional knowledge is difficult due to the need to identify an original inventor when one or more families or tribes may share the same knowledge. In addition, meeting the test of non-obviousness is also challenging as traditional practices are considered unscientific due to the characteristics of oral tradition and the lack of documented evidence of much traditional knowledge.

The view that IPR laws are generally inappropriate and inadequate to protect the rights and resources of traditional knowledge-holders and local communities is shared by a number of developing countries, NGOs and academics. Some authors have put forward the concept of Traditional Resource Rights, which recognise “the inextricable link between cultural and biological diversity and sees no contradiction between the human rights of indigenous and local communities, including the right to development and environmental

41 Sheldon J W and Balick M J, Ethnobotany and the search for balance between use and conservation, in Swanson T (ed.), ‚Intellectual property rights and biodiversity conservation — An interdisciplinary analysis of the values of medicinal plants , Cambridge University Press, 1995.

42 Gupta A K, Rewarding conservation of biological and genetic resources and associated traditional knowledge and contemporary grassroots creativity, Indian Institute of Management, January 2003.

43 See n.30. See also Gollin M A, Biopiracy: The Legal Perspective, American Institute of Biological Sciences, 2001.

44 DeGeer M E, Biopiracy: The Appropriation of Indigenous Peoples Cultural Knowledge, New England Journal of International & Comparative Law, Vol. 9:1, 2002.

conservation"[45]. Others follow a more pragmatic approach in reviewing IPR systems to make them work for the protection of genetic resources and traditional knowledge, both in a positive way, as an incentive for its conservation and protection, and in a negative way, by precluding others from patenting them.

There have been numerous examples of controversial cases of patents over genetic resources and traditional knowledge, most of them in the US, a non-Party to the CBD. Some examples are[46]: a US patent granted in 1995 for the healing properties of turmeric, known for centuries in India; a US patent on the ayahuasca plant, considered sacred and used for medicinal purposes by Amazon s indigenous peoples; and a US patent for the use of a combination of herbal compositions as anti-diabetic agents that have been in use and are also well-documented in Indian scientific literature and ancient texts for the same anti-diabetic properties. Another example regarding research and development of commercial products based on traditional knowledge associated to a specific plant in Southern Africa, and the role played by IPRs, is included below, together with an example of patents over GM crops in India.

The case of the San people and the hoodia plant: Biodiversity, traditional knowledge and IPRs in Southern Africa

The San people are indigenous inhabitants of Southern Africa, numbering around 100,000 across South Africa, Botswana, Namibia and Angola. They formed the Working Group of Indigenous Minorities in Southern Africa (WIMSA) to protect their rights and interests. In 1997 the WIMSA Board of Trustees announced that it would no longer allow free access to the San by the media or researchers, and drew up contracts for payment in return for access to their lives and ancestral knowledge[47].

Hoodia is a succulent plant that grows throughout the semi-arid areas of Southern Africa. The San have traditionally used Hoodia stems to stave off hunger and thirst during their long journeys, as it acts as an appetite suppressant. The active ingredient in Hoodia and its possible use as a slimming drug have attracted the attention of pharmaceutical companies. The active ingredient of the Hoodia cactus was identified by the Council for Scientific and Industrial Research in South Africa (CSIR). They passed on their work to British company Phytopharm for further development. Phytopharm then sold the exclusive global license to commercialise the drug to Pfizer, for 21 million US dollars[48].

45 Posey D and Dutfield G, Beyond Intellectual Property: Towards Traditional Resource Rights for Indigenous Peoples and Local Communities, IDRC, 1996.

46 Kothari A and Anuradha R V, Biodiversity and Intellectual Property Rights: Can the Two Co-Exist?, 2(2) Journal of International Wildlife Law & Policy (1999).

47 Berne Declaration, Stolen Knowledge: Article about the Hoodia Cactus, September 2001.

48 Indigenous plant benefits San, SouthAfrica.info reporter, 23 March 2003, see at http://www.southafrica.info/doing_business/economy/success/medicine_270303.htm

The chronology of events in this case shows the difficulty and the long duration of negotiations related to benefit-sharing agreements, especially considering that access to the resource was negotiated in the context of lack of specific legislation in South Africa, as well as lack of involvement of the knowledge-holders. A summary of events is listed below:

- 1996: CSIR scientists isolated the Hoodia s hunger-suppressing chemical component, or P57, and patented it.
- 1997: CSIR licensed to UK-based firm Phytopharm the further development and commercialisation of P57 (but CSIR retained the patent).
- 1998: Phytopharm licensed drug giant Pfizer to develop and market P57.
- July 2001: a Pfizer spokesman discussing research on P57 mentioned the link to the San people but said the San were extinct .
- November 2001: the South African San Council is established. It opened talks with the CSIR demanding recognition of their knowledge and a share of the benefits. The South Africa San Council negotiated with the CSIR on behalf of the San in Angola, Botswana, Namibia, Zambia and Zimbabwe, as the San will share profits across borders.
- March 2003: the South African San Council and the CSIR signed an agreement recognising and rewarding the San people as traditional knowledge-holders, with a reported share of up to eight percent of profits from the drug derived from the Hoodia plant[49]. The CSIR agreed to pay the San eight percent of milestone payments, a payment to be made by its licensee Phytopharm during the drug s clinical development over the following 3-4 years, with the further agreement that when the drug is marketed, possibly in 2008, the San will get six percent of royalties[50].
- July 2003: Phytopharm announced that Pfizer had decided to discontinue the clinical development of P57, returning the right to Phytopharm.
- 2004: Canadian and US companies market Hoodia Gordonii coming directly from South Africa[51].

The agreement reached includes[52] the commitment of both parties “to the conservation of biodiversity, including by applying legal best practices to the collection of any plant species for observation, and by ensuring that no negative environmental impacts will flow from the proposed bioprospecting collaboration”. In addition, the CSIR acknowledged

49 CorpWatch press release, South Africa: Indigenous Group Wins Rights to its Healing Herbs, 28 March 2003.

50 Id.

51 Press release Appetite Be Gone with Hoodia Gordonii Appetite Suppressant, of 21 February 2004, see at http://www.prweb.com/releases/2004/2/prwebxml105321.php See also http://www.hoodia-dietpills.com/, accessed in November 2004.

52 As reported by Dr Terblanche, Executive Director of CSIR Bio/Chemtek, at the Symposium on Food Security and Biodiversity, 16 October 2003, Basel, Switzerland. See at http://www.benefitsharing.org/pdf/Presentation_Petro_Terblanche.pdf

"the existence and the importance of the traditional knowledge of the San people, and the fact that such body of knowledge, existing for millennia, predated scientific knowledge developed by Western civilization over the past century".

The San agreement has been criticised for a number of reasons[53]: (i) the San will receive less than 0.003 per cent of net sales of the product, which will come from the CSIR s share, while profits received by Phytopharm and Pfizer will remain unchanged (Pfizer and Phytopharm are not only exempt from sharing their benefits but also protected by the agreement from any further financial demands by the San); (ii) the agreement explicitly prevents the San from using their knowledge of Hoodia in any other commercial application; and (iii) the administration of the benefits to come, including the determination of beneficiaries and apportioning of the funds across countries and within different communities[54], are expected to create conflict. The wider implications and concerns raised by this agreement relate to the patenting and privatisation of knowledge in communities where the sharing of knowledge is part of their culture and central to their way of life. On the other hand, this agreement has set an important international and national precedent in South Africa and neighbouring countries[55].

The case of Bt cotton in India: GMOs, decision-making and multinational corporations

Monsanto pioneered the introduction of a protein of the bacterium Bacillus thuringiensis (Bt), into cotton using genetic engineering methods. The result, Bt cotton, is claimed to control pests such while reducing the need for pesticides. However, the Bt cotton technology has also been criticised for promoting monoculture, as widespread propagation of genetically modified (GM) varieties precludes the use of other varieties of crops in the same area. In addition, such agricultural techniques are especially vulnerable to extensive damage by pests and climatic changes like drought. While it has been argued that all the countries that have introduced Bt cotton have derived significant and multiple benefits [56], such as yield increases and reduced production, with benefits between 1998 and 2001 having been estimated at US$1.7 billion[57], doubts have also been cast on the long-term benefits of Bt cotton, as a study in India found that the protection afforded by Bt gene would only last for a maximum period of six years[58].

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53 Wynberg R, Sharing the crumbs with the San, 2002, available at http://www.biowatch.org.za/csir-san.htm

54 It has been agreed to place the potential funds to be received into a San Hoodia Benefit Sharing Trust .

55 See n.53.

56 James C, Global Review of Commercialized Transgenic Crops: 2001 Feature: Bt Cotton. International Service for the Acquisition of Agri-Biotech Applications, ISAAA Briefs No. 26. 2002, ISAAA SEAsiaCenter, Philippines.

57 Id.

58 Chandrasekar K and Gujar G T, Bt Cotton Benefits Short-lived: Study, Indian Agricultural Research Institute, as reported in the Financial Express (India), 11 February 2004.

India is the third largest producer of cotton, with around 15 per cent of global production. Bt cotton was first approved for commercial release in the US in 1996, where Monsanto supplies 85 per cent of the cottonseed. In 2002, the first approval for commercial release in India was granted by the Ministry of Environment and Forests, on the basis of a three-year trial period in six states. At the same time, it was reported that Bt cotton had been illegally planted over several years in various regions in India. The debate and controversy surrounding the approval of Bt cotton in India linked a number of policy issues and factors such as the nature of the GM technology, the control of agriculture by multinationals, and the effectiveness of the regulatory process[59]. It has also been argued that the information available to the public regarding Bt cotton and its effects was incomplete, irrelevant, or obfuscated [60], which resulted in shortcomings in addressing the relevant technological and societal issues during the decision-making process to authorise the commercial release of Bt cotton. Activists were very critical of the use of scientific arguments and data by industry, concluding that India was an example of corporate promotion of "an unnecessary, untested, hazardous technology through pseudo science"[61], as yields of Bt cotton fell by 80 per cent and left farmers with significant economic losses[62].

The chronology of events listed below shows the main milestones leading to the decision to authorise the commercial release of Bt cotton in India. Civil society groups have characterised the regulatory process by a lack of transparency and public debate over this controversial new technology. Moreover, the Indian government has been criticised for its handling of the Bt cotton field trial evaluations by Monsanto [63]:

- April 1998: Monsanto is given permission to conduct the first field trials of Bt cotton in India;
- November 1998: Thousands of farmers occupied and burned down Bt cotton trial fields in Karnataka as part of Operation Cremation Monsanto ;
- January 1999: the Research Foundation for Science, Technology and Ecology went to the Supreme Court challenging the "illegality" of the field trials that had been authorised;
- July 2000: Large-scale field trials were allowed, including seed production at 40 sites in six states. The permission was granted based on "totally confidential" data from the small trials that allowed regulators to infer that Bt Cotton was "safe." A Committee to "independently" monitor and evaluate the large scale field trials was set up;
- June 2001: Field trials of Bt Cotton were extended by another year;

59 Scoones I, Regulatory manoeuvres: The Bt cotton controversy in India, Institute of Development Studies, Working Paper 197, UK, August 2003.

60 Bharathan G, Bt-cotton in India: Anatomy of a controversy, Current Science, Vol. 79, No. 8, 25 October 2000.

61 Shiva V, Biotech Wars: Food Freedom Vs Food Slavery, Research Foundation for Science, Technology and Ecology, India, at http://www.vshiva.net/aticles/biotech_wars.htm

62 Id.

63 Chronology of Bt Cotton in India, India Resource Center, 25 March 2002.

- October 2001: Unauthorised commercial Bt cotton farming is discovered in Gujarat. The Indian government ordered those Bt cotton fields to be burnt but no action is taken after a farmers protest.
- November 2001: NGO Gene Campaign filed a case in the Delhi High Court charging the Government with negligence in allowing large-scale field trials to be conducted without appropriate monitoring, regulation and safety precautions. The petition demanded that GMOs be released only after a rigorous regulatory procedure and an evaluation by an independent regulatory agency.
- February 2002: The Indian Council of Agricultural Research (ICAR) submitted a positive report on the field trials of Bt cotton to the Ministry of Environment.
- March 2002: The Genetic Engineering and Approval Committee (GEAC) of the Ministry of Environment approved the commercial use of Bt cotton.

In April 2003, the Standing Parliamentary Committee in India reported that Bt cotton appeared to perform "only marginally" better than conventional varieties, both in terms of productivity and resistance to bollworm infection[64]. The Committee asked the government to set up an independent team of experts to re-evaluate the cotton variety s economic viability and possible environmental impact. In addition, India-based NGO Gene Campaign published a study[65] with field data showing that the first harvest of Bt cotton had failed, and that the GM crop had proved to be significantly more expensive than traditional varieties, leaving farmers in debt . Gene Campaign demanded that Monsanto pay compensation to farmers that had suffered losses due to Bt cotton. This information contradicted claims by Monsanto that the three Bt cotton varieties approved for commercial release had increased farmers incomes and led to reduced pesticide use by 65–70 percent while increasing yields by 30 percent.

In November 2003, Gene Campaign organised a national symposium on the relevance of GM technology to Indian agriculture and food security, which resulted in a set of 20 recommendations which included the need for a national biotechnology policy[66]. The Indian government disagreed on the need for a separate biotechnology policy and Gene Campaign filed a public interest lawsuit in the Supreme Court of India challenging the constitutionality of India s Rules on GMOs. The main requests of the legal challenge, filed in January 2004, were[67] the formulation of a national policy on GMOs, through a consultative process, and a moratorium on approvals and field trials of GMOs until a sound regulatory and monitoring system is in place.

64 BRIDGES Trade BioRes, Bt cotton remains highly controversial in India, Vol.3 No.8, 1 May 2003.

65 Sahai S and Rahman S, Performance of Bt Cotton- Data from First Commercial Crop, 38 Economic & Political Weekly, 26 July 2003.

66 Gene Campaign, Notice Issued to Government on PIL on GM Technology, see at http://www.genecampaign.org/news/notice_pil.html

67 Id.

This case illustrates the web of interconnections between the influence a powerful multinational corporation at the forefront of developments in biotechnology, the shortcomings of a regulatory regime, and the role of the public and civil society in challenging political and administrative processes and decisions related to economic, environmental and health risks with a significant impact on rural livelihoods.

Both cases raise issues that are at the heart of the international debate on biodiversity, traditional knowledge and intellectual property rights. On the one hand, they provide valuable experience and information on real life situations and the application of the global rules under development. However, on the other hand, these cases alert us to significant risks and shortcomings in dealing with these emerging issues, and the real problems they are creating.

From a legal perspective, these cases illustrate the complex and highly technical nature of the new frameworks to deal with benefit sharing, in the case of the Hoodia plant and the San people, and the regulation and promotion of a new technology, in the case of Bt cotton in India. The provision of information and opportunities for effective public participation lacked in both cases, which involved sizeable multinational corportations. In the Hoodia case, the company eventually acknowledged the claims of local communities and reached and agreement with their representatives. This benefit sharing agreement has received criticisms and praise from different sectors, but it has certainly broken new ground and it will an important precedent for future negotiations. Its application will determine the effectiveness of the arrangement, which will also provide lessons to be learned for future agreements of this kind.

A different issue which should also be studied in the future is the effect that the new international regimes on agro-biodiversity, traditional knowledge, and IPRs, are having in the way local and indigenous communities operate. Global rules promote the privatisation and commercialisation of knowledge and wild varieties, which represent fundamental changes to the culture and values of many indigenous peoples and communities. Global trade and economic rules also make corporations stronger, and their involvement in local and internationl politics and policies is also increasing. Whether the new international regimes on biodiversity, trade, and IPRs will provide adequate checks and balances between regulations, corporations, citizens and consumers remains to be seen, but if we get it wrong there will not be a second chance for many communities, wildlife, and crops.

4. International governance of biodiversity and intellectual property rights

This section attempts to present an overview of the main international fora and debates surrounding the regulation of biodiversity and IPRs, focusing on ongoing discussions and negotiations at the CBD, WTO, and WIPO. This section summarises and highlights the main positions of countries, NGOs, and the private sector, regarding the relationship between biodiversity, trade and IPRs, and the way it should be addressed and regulated.

4.1 The CBD and IPRs

The Convention on Biological Diversity (CBD) entered into force in December 1993 and has 188 Parties, which makes it a truly global treaty . The CBD aims are to conserve biodiversity, ensure its sustainable use, and achieve a fair and equitable sharing of any benefits derived from biological genetic resources. The reference to fairness and equity represents an innovative element in a biodiversity convention, marking a shift from previous wildlife agreements focusing primarily on nature conservation. The CBD introduces an ethical element as regards the way of sharing the benefits derived from permitted uses of biological diversity.

The CBD defines genetic resources as genetic material of actual or potential value of plant, animal, microbial or other origin, containing functional units of heredity [68]. The scope of the biological diversity covered by the CBD encompasses species, populations and other biotic components found in terrestrial, marine and other aquatic ecosystems. As the CBD Preamble recognises, there is still a widespread lack of information and knowledge about biodiversity, although there is concern about its significant reduction and the need to anticipate, prevent and attack the causes of its decline at source.

The scope and objectives of the CBD reflect to a great extent the position of developing countries during the negotiations of this convention, as they host the majority of the biodiversity on the planet. One of the objectives of the G-77[69] during the negotiations of the CBD was to ensure that the importance and value of biological resources was adequately recognised in the CBD. Developing countries set as conditions for their participation in the CBD negotiations that the new treaty should include specific obligations and measures

68 Article 3, CBD.

69 The Group of 77 (G-77) was established in 1964 by seventy-seven developing countries. It is the largest coalition of developing countries in the United Nations and its aim is ,to provide the means for the developing world to articulate and promote its colelctive economic interests and enhance its joint negotiating capacity on all major international economic issues in the UN system . See http://www.g77.org

regarding three types of access : (i) access to genetic resources; (ii) access to technology (including biotechnology); and (iii) access of countries providers of genetic resources to the benefits derived from the use of their genetic material[70].

The CBD is the first international treaty to link access to genetic resources and the right to the equitable sharing of benefits related to those resources, which can be found in Articles 1, 8(j), 15, 16 and 19 as the main CBD provisions on access to genetic resources and equitable benefit sharing. The CBD establishes the principle of national sovereignty as the basis for the regulation of access to genetic resources and benefit sharing. States are sovereign to regulate access, including who should give consent, who should participate in the negotiation of the terms and conditions of that access, and who should receive a fair and equitable share of the benefits

More than ten years after the entry into force of the CBD, achieving its three objectives remains a challenge. The circumstances that led to the adoption of this international convention have not greatly improved as we still lack basic biodiversity data such as the total number of species on Earth or how many become extinct each year. However, a very specific objective was set at the 2002 World Summit on Sustainable Development (WSSD): to achieve a significant reduction of the current rate of biodiversity loss by 2010 . At the WSSD, the Johannesburg Plan of Implementation was adopted, including a section on biodiversity which states that the current trend of biodiversity loss due to human activities can only be reversed if the local people benefit from the conservation and sustainable use of biological diversity, in particular in countries of origin of genetic resources, in accordance with Article 15 of the CBD [71].

The Johannesburg Plan of Implementation went beyond the CBD as countries agreed on the need to negotiate an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources [72]. CBD COP-7, in February 2004, discussed and adopted the terms of reference for the negotiation of an international regime on access to genetic resources and benefit sharing, with two negotiation meetings scheduled before the next COP in 2006. Agreement on the scope, elements and modalities of such a regime will be hard to achieve judging by the very difficult negotiations at COP-7 on the terms of reference for the negotiations themselves. CBD Parties could not agree on whether the international regime should be legally binding or not, an issue which remains open and which could crucially determine the way the negotiations are conducted in the coming years.

70 A Guide to the Convention on Biological Diversity , Environmental Policy and Law Paper No. 30. IUCN Environmental Law Centre, Gland (Switzerland), 1996.

71 Paragraph 44 of the WSSD Plan of Implementation. A/CONF.199/20.

72 Id, para.44(o).

The only explicit reference to IPRs in the CBD is found in Article 16(5), which recognises that patents and other intellectual property rights may have an influence on the implementation of this Convention , and so CBD Parties must co-operate in order to ensure that such rights are supportive of and do not run counter to its objectives . IPRs are also mentioned in relation to developing countries access to technology protected by patents and other IPRs, as well as to the transfer of that technology to developing countries. Article 16(3) includes another linkage between access to genetic resources and IPRs as it establishes that developing country providers of genetic resources should have access to, and transfer of, the technology that uses those resources.

Since the establishment of the WTO and the entry into force of the TRIPS Agreement, there has been a call, mainly be developing countries, to explore the relationship between CBD and IPRs. In parallel, CBD COP decisions[73] have stressed the need to gather information on the impact of IPRs on achieving the objectives of the CBD[74], and to explore the relationship between the Convention and the TRIPS Agreement[75]. The relationship between the two regimes has been partly facilitated by the fact that the CBD Secretariat is admitted as an observer to the meetings of the WTO Committee on Trade and Environment, although the application to get observer status at the TRIPS Council has not yet been resolved[76] [77].

CBD Parties have not been able to reach agreement on the role of IPRs in the application of the access and benefit sharing provisions of the CBD, with a number of areas having been identified as needing further research. These are[78]: (i) the use of IPRs to strengthen prior informed consent (by requiring that IPR applicants submit evidence that the prior consent has been obtained from the owner of the resource or traditional knowledge); (ii) the role of IPRs in the protection of traditional knowledge; and (iii) the scope and impact of IPRs on legitimate interests of other stakeholders.

In 2002, the Sixth meeting of the Parties to the CBD (COP-6) adopted the non-binding Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits[79]. They include IPRs as a possible benefit derived from the utilisation of genetic resources. Appendix I of the Bonn Guidelines recommends that it should be agreed whether IPR applications based on the genetic materials accessed are allowed and, if so,

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73 Handbook of the Convention on Biological Diversity , CBD Secretariat, 2nd edition, 2003, pp.176–177.

74 CBD COP Decisions II/12 and II/17, para.1.

75 CBD COP Decisions III/17, IV/15, para.9; V/26B, para.2; and VI/24D.

76 CBD COP Decisions V/26B, para.4 and VI/24D, para.1. The latest official application for observer status in the TRIPS Council was made in July 2000.

77 See IP/C/W/52/Rev.10, of 26 April 2002.

78 Report of the Panel of Experts on Access and Benefit-Sharing , UNEP/CBD/COP/5/8, of 2 Nov. 1999, paragraphs 132–138.

79 COP Decision VI/24 Part A.

under what conditions. The possibility of joint ownership of relevant intellectual property rights also appears in the indicative lists of monetary and non-monetary benefits included in Appendix II of the Bonn Guidelines.

COP-6 invited CBD Parties to[80] encourage the disclosure of the country of origin of genetic resources and traditional knowledge in IPR applications, such as patents , that make use of those resources and knowledge. One of the objectives of this disclosure would be to help track compliance with the CBD requirement that access to genetic resources must be based on prior informed consent and mutually agreed terms.

COP-6 also addressed the issue of sui generis or specific and distinct regimes for the protection of traditional knowledge[81], and the outcome was also to invite CBD Parties to[82] encourage the disclosure of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for IPRs that use of such knowledge, and to take into account traditional knowledge when examining the novelty and inventive step requirements in patent applications. The language used in the CBD COP decisions reflects the difficulty to reach agreement in these matters to give a clear policy direction. The consensus rule of decision-making within the CBD framework leads to most compromises being made close to the common lowest denominator among the 188 Parties, which is why on a controversial issue such as IPRs, no stronger terms than encourage , invite or take into account are agreed upon, as some countries would like to delete these reference while others would like to make them stronger. However, they should also be read as reflecting a trend in international discussions that is gaining momentum and which groups of countries are defending in different fora, which may lead to more binding obligations in the future.

In February 2004, COP-7 continued this debate and CBD Parties were invited to recognise that traditional knowledge, "whether written or oral, may constitute prior art"[83]. Patents are subject to the full disclosure of the invention, which contributes to further innovations and promotes the advancement of science and technology. Disclosure is therefore crucial to determine whether the claimed invention is new and non-obvious , as information in the public domain cannot be patented. Disclosing the traditional knowledge used in an invention or part of prior art creates an incentive for the maintenance of traditional knowledge systems. In addition, the status of traditional knowledge would be promoted by being widely and universally accepted within the IPR protection system[84].

80 Id, Part C, paras.1 and 2.

81 CBD COP Decision VI/10F, para.34.

82 Id, at paras.46 and 48.

83 Decision VII/19, Part E, para. 3

84 Ruiz M, The international debate on traditional knowledge as prior art in the patent system: Issues and options for developing countries, CIEL, October 2002.

Current priorities regarding these issues include consideration of the disclosure of the origin of genetic resources and associated traditional knowledge in IPR applications, including a proposed international certificate of origin, source or legal provenance of the resources and associated knowledge [85], which could be used in patent applications to prove that the resources and/or associated knowledge were legally acquired.

The CBD system has not stopped the loss and destruction of biodiversity. New global biodiversity targets recognise the need to fully involve local and indigenous peoples and communities in the governance regime of CBD implementation if we are to at least reduce the rate of biodiversity loss. The CBD is based on national sovereignty, and national governments are to regulate access to genetic resoruces and benefit sharing, but the equity element of ensuring a fair and equitable sharing of the benefits derived from biodiversity has not been adequately addressed yet and is partly responsible for the lack of progress in the conservation and sustainable use of biodiversity, the other two objectives of the CBD.

4.2 CBD and WIPO

The CBD works closely and exchanges information with the World Intellectual Property Organization (WIPO) on these matters. CBD COP-6 asked WIPO to prepare a technical study on possible methods for requiring the disclosure in patent applications of the genetic resources used; their country of origin; any associated traditional knowledge and its source; and evidence of prior informed consent[86]. A Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge was considered by WIPO s General Assembly at the end of September 2003[87] and submitted to CBD COP-7 in February 2004 as a technical reference document and not to advocate any particular approach nor to expound a definitive interpretation of any treaty [88]. COP-7 invited WIPO to examine a number of specific questions regarding access to genetic resources and the disclosure requirements in IPR applications[89], including: practical options for IPR application procedures with regard to the trigger of disclosure requirements; implications for the functioning of disclosure requirements in various WIPO treaties, and IPR issues raised by the proposed international certificate of origin/source/legal provenance; and regularly provide reports to the CBD on this work, in the spirit of mutual supportiveness .

85 COP Decision VII/19, Part E, para.7.

86 CBD COP Decision VI/24C, para.4.

87 WO/GA/30/7 Add.1

88 UNEP/CBD/COP/7/INF/17, of 15 December 2003.

89 CBD COP Decision VII/19, Part E, (preamble and paragraph 8).

WIPO is a UN specialised agency that administers 23 international treaties related to IPRs[90], and has 180 member states. Its mandate is the promotion and the protection of intellectual property throughout the world through co-operation among states and, where appropriate, in collaboration with any other international organisations[91]. Interestingly, WIPO is the only UN agency that is largely self-funding, as it finances its activities from the revenue it obtains through the provision of services to the private sector in the form of international registration and filing of patents, trademarks, and designs: 91 per cent of WIPO s budget comes from fees paid by the private sector for its services under the Patent Cooperartion Treaty, with contributions by member states amounting to less than 10 per cent of the agency s overall budget[92].

One of WIPO s programmes (Global Intellectual Property Issues) has a sub-programme on Biological Diversity and Biotechnology . At the WIPO General Assembly in 2000, it was decided that a distinct body should be established to facilitate discussions about intellectual property and genetic resources among WIPO member states. To this end, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established, with a work programme which included the determination of the scope of traditional knowledge in order to discuss the type of protection which can be provided by IPRs; the consideration of existing and new criteria which would allow the effective integration of data about disclosed traditional knowledge into searchable prior art; and the consideration of ways to assist traditional knowledge holders in relation to the enforcement of IPRs, in particular by assisting them to strengthen their capacity to enforce their rights.

At the first session of the IGC, it was agreed that the Intergovernmental Committee should address the issues before it in conjunction with the CBD Secretariat as its work should be consistent with and complementary to the work carried out by the CBD, both on access to genetic resources and on the implementation of Article 8(j) on traditional knowledge. The CBD COP invited WIPO to take account of the lifestyles and the traditional systems of access to and use of the knowledge, technologies and practices of indigenous and local communities in its work, as well as the relevant recommendations of the COP[93].

The IGC has met seven times since September 2000 and has addressed the protection of traditional knowledge both through conventional IPR systems and through distinct sui generis systems of protection. The IGC has been working on the steps that need to be taken to safeguard the interests of the communities who have developed and preserved traditional knowledge and cultures. In July 2003, the IGC Secretariat produced a composite study which included approaches to definitions of traditional knowledge,

90 WIPO s mission is to encourage creative activity, while its mandate is to promote the protection of intellectual property throughout the world (Visions and Strategic Direction of WIPO, 1999).

91 WIPO Constitution Online,. See at http://www.wipo.int/clea/docs/en/wo/wo029en.htm#P68_2905

92 WIPO Press Release PR/2001/288, of 25 September 2001.

93 CBD COP Decision IV/9, para.16.

national experiences in its protection and an analysis of elements of a sui generis system. This document drew together the information about the intellectual property protection of traditional knowledge that had been considered by the Committee, including surveys of national mechanisms for the protection of traditional knowledge, specific sui generis laws, case studies on the use of intellectual property to protect traditional knowledge, and an analysis by the Secretariat of issues such as operational definitions and elements of sui generis protection of traditional knowledge, as well as material gathered in consultations with holders of traditional knowledge that the Secretariat conducted in 1998-1999.

The IGC was mandated by WIPO s General Assembly as a forum for discussion of these issues and the General Assembly had to consider whether to renew its mandate at a meeting in September 2003. Extensive debate was held over the IGC s future direction, including the possibility of moving beyond the initial mandate of serving as a forum for discussion. There was strong support for the position that the IGC should move towards concrete outcomes within the next two years, focusing on the international aspects of protecting traditional knowledge, but views differed over the appropriate form and legal status of these outcomes[94]. Countries were strongly divided over pursuing an international regime for the protection of genetic resources, traditional knowledge and folklore. While the African Group demanded that negotiations on a legally-binding regime begin in the next two years, Latin American and Asian countries proposed the development of a set of principles with the possibility of a binding regime. In addition, the US opposed the negotiation of a binding regime at the current time.

The WIPO General Assembly meeting in late 2003 extended the mandate of the IGC for a further two years. The IGC was requested to accelerate its work and to focus on the international dimension of intellectual property and genetic resources, traditional knowledge and folklore. The expected outcome of the IGC s work to be included in the mandate was very contentious. While many developed countries continued to resist demands by the African Group to include references to a legally binding instrument, Brazil, Andean and Caribbean states reiterated their call for joint recommendations as the IGC s outcome. There was final agreement on the statement that no outcome of its work is excluded, including the possible development of an international instrument or instruments [95]. In addition, the mandate stated that discussions in the ICG should be without prejudice to the work in other fora , which could provide an opening for developing countries to advance their agenda in the TRIPS Council. Some developing countries long opposed to addressing these issues at the WTO are reconsidering their positions on the scope of future TRIPS negotiations given the inclusion of stricter IPR requirements in bilateral and regional trade agreements with countries such as the US, EU and Nordic countries, and also in the light of the ongoing patent agenda negotiations in WIPO.

94 Next steps for international protection of traditional knowledge in view, WIPO Update 201/2003, of 21 July 2003.

95 See BRIDGES Trade BioRes, Vol. 3 No. 17, of 3 October 2003.

At the IGC meeting in March 2004, Brasil, the African Group and other developing countries questioned the mandate of the IGC to respond to the invitation by CBD COP-7 to assess the interrelation between access to genetic resources and possible disclosure requirements in IPR applications. Those countries also expressed their concern about the lack of co-ordination between the IGC and other debates that are currently taking place within WIPO, such as the negotiations on the Patent Cooperation Treaty regarding patents. Views on the preference for the TRIPS Council to deal with these issues were also expressed at the March 2004 meeting[96].

The latest IGC meeting was held on 1–5 November 2004, after WIPO s General Assembly adopted a decision in October 2004 to consider the integration of a development agenda into all WIPO bodies[97], and to establish a process to respond to the request from CBD COP-7 regarding disclosure of origin of biodiversity and traditional knowledge in patent applications. However, work under the new mandate needs to be further defined and the long-term strategy to protect genetic resources and traditional knowledge has not been completely established[98]. The seventh session of the IGC considered a set of draft provisions on objectives and principles for the protection of traditional knowledge against misappropriation and misuse. Further comments on those draft objectives and principles have been invited (until 25 February 2005). Other key issues at this meeting were the relationship between traditional knowledge and the patent system, and the appropriate legal form of protection for such knowledge[99]. There was no consensus on the future work of the IGC in the area of genetic resources so no decision was taken at the November meeting on this issue, although it will be included in the agenda of the next IGC meeting.

4.2.1 Key positions at the IGC

One of the main outcomes of recent IGC meetings was to accelerate its work on the protection of traditional knowledge. Brasil defends that developing countries should not have to take on new obligations in respect of conventional types of IPRs to protect traditional knowledge[100]. They argue that any proposed combined approach to the protection of that knowledge would necessarily have to include the use of defensive protection measures, such as disclosure of origin and prior informed consent requirements in patent laws , as sui generis regimes for TK are not a replacement or substitute for measures of a defensive nature, such as the use of disclosure of origin, prior informed consent and benefit sharing requirements in patent laws [101]. Brasil and the African Group agree that

96 See BRIDGES Weekly Trade News Digest Vol. 8 No.11, of 24 March 2004.

97 See BRIDGES Trade Biores, Vol.4 No.18, of 8 October 2004.

98 Analysis of selected documents for the Seventh Session of the IGC, CIEL Brief, October 2004.

99 See BRIDGES Trade BioRes, Vol. 3 No.21, of 19 November 2004. The report of the meeting is not available yet.

100 Meeting report, WIPO/GRTKF/IC/6/14, of 14 April 2004, para.69.

101 Id.

the relationship between the CBD and WIPO processes on access to genetic resources, benefit-sharing, the protection of traditional knowledge and IPRs should not go beyond a mutual exchange of information .

India considers that to realise the objectives of traditional knowledge protection the IGC would need to utilise fully the options available under the IP system [102]. India argues that the IGC also needs to address the issue of misappropriation, not only to prevent future misappropriation but also to find ways and means to provide solutions for past wrongs[103]. They argue the need for an agreed international framework for fast invalidation procedures of large-scale misappropriation , a problem that India has closely experienced due to numerous patents on their plants and crops. India also supports internationally binding sui generis legal instruments on traditional knowledge.

The EU has expressed its support for work towards the development of international sui generis models for the legal protection of traditional knowledge[104], while the US supports the use of traditional IPR laws to protect inventions related to traditional knowledge, but remained cautious at the IGC meeting in March 2004 on the possibility of establishing new IPR laws as they may conflict with the principles of traditional IPR laws[105]. This position points towards concerns from the US that exploring new ways of protecting traditional knowledge by using IPRs could affect current patent rules. The US did not support the recognition of specific, intangible property rights in traditional knowledge that are outside of the scope of traditional IPR laws [106]. They added that any new form of intangible property rights applying to traditional knowledge had the potential to take vast amounts of material out of the public domain potentially for indefinite periods . Furthermore, the US supports to focus and accelerate the work of the IGC on the protection of traditional knowledge as they maintain that WIPO is the appropriate forum for this work.

The IGC will compile legislative and policy options for the protection of traditional knowledge providing the basis for national or international measures, without excluding a possible international instrument for the protection of traditional knowledge and folklore. The timeframe for these activities is the extended mandate of the IGC, i.e. until the end of 2005[107].

At the heart of WIPO debates on biodiversity, traditional knowledge and IPRs lies a marked difference in views as to the role that such agency should place in the protection of traditional knowledge and the regulation of access to genetic resources, which WIPO body should take the lead on its work, and the co-ordination between WIPO and the CBD

102 Id. at para.81.

103 Id.

104 Id, at para.75.

105 Id, at para.76.

106 Id.

107 See ICTSD, Trade BioRes, Vol. 4, no. 6, 2 April 2004.

system. Concerns have also been expressed regarding the pro-IPRs inherent bias of WIPO, due to its mandate and objectives.

4.3 WTO and CBD

In November 2001, the WTO held its Fourth Ministerial Conference in Doha, Qatar, where ministers agreed to launch international trade negotiations under the so-called Doha Development Agenda . The Doha Ministerial Declaration provided the mandate for global trade debates on a range of issues, including on the need to[108]: (i) continue the review of Article 27.3(b) of the TRIPS Agreement; (ii) examine the relationship between the TRIPS Agreement and the CBD; and (iii) consider the protection of traditional knowledge and folklore. The Ministerial Conference held in Cancún, Mexico, in September 2003, failed to move these negotiations forward. A revised negotiating package was agreed in July 2004, moving the final deadline for concluding the Doha negotiations from 1 January 2005 to the end of that year, as the next WTO Ministerial Conference will take place in Hong Kong in December 2005.

The TRIPS Agreement does not include any provision related to the CBD requirements on access to genetic resources and benefit-sharing or protection of traditional knowledge, but the Doha Declaration has reinforced the TRIPS review with its mandate to consider the protection of traditional knowledge, and the relationship between the TRIPS Agreement and the CBD.

A number of CBD COP Decisions have also considered the need to address linkages between WTO trade issues and the CBD. As early as CBD COP-3, the CBD Secretariat was requested to co-operate closely with the WTO through the Committee on Trade and Environment to explore the extent to which there may be linkages between Article 15 (on access to genetic resources) and relevant articles of TRIPS[109]. The relationship between IPRs and the relevant provisions of TRIPS and the CBD was reaffirmed in more detail in CBD COP-5 in 2000, which invited the WTO to acknowledge the relevant provisions of the CBD, take into account the fact that certain TRIPS and CBD provisions are interrelated, and further explore their linkages. The importance of sui generis systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits were also reaffirmed at that meeting[110]. Later on, in 2002, COP-6 would further develop these concepts by adopting the Bonn Guidelines and acknowledging the interrelationship between the CBD and other relevant international regimes, such as WIPO and the FAO International Treaty for Plant Genetic Resources for Food and Agriculture[111].

108 WTO, Doha Ministerial Declaration, paragraph 19.

109 CBD COP Decision III/15, para.8.

110 CBD COP Decision V/26, para.B.1–4.

111 CBD COP Decision VI/24, para D.10.

The TRIPS Council has met in several occasions since the Doha ministerial to discuss the relationship between TRIPS and the CBD, and the protection of traditional knowledge. In the context of these meetings, the WTO Secretariat published a note in August 2002 on the protection of traditional knowledge and folklore summarising the issues raised and the positions observed[112]. This paper covered the protection of traditional knowledge, the granting of patents over that knowledge, prior informed consent, and benefit-sharing. In addition, the CBD Secretariat submitted to the TRIPS Council updated information on CBD activities, the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge[113]. More recently, the CBD Secretariat has repeatedly applied to the TRIPS Council for observer status but to date this request has not been granted.

A number of developing and developed countries have made submissions and proposals to the TRIPS Council on traditional knowledge, and on the relationship between the CBD and TRIPS, some of which are summarised below:

4.3.1 Main positions on the protection of genetic resources and traditional knowledge:

- The African Group[114] has proposed to classify traditional knowledge as a category of IPR. In addition, they have further proposed that the WTO should adopt a Decision on Traditional Knowledge establishing a WTO Committee on Traditional Knowledge and Genetic Resources to oversee the protection of traditional knowledge and enforcement of rights of WTO Members. Underpinning this proposal, which includes a draft decision annexed, was the Group s emphasis that the protection of genetic resources and traditional knowledge will not be effective until international mechanisms are implemented within the TRIPS framework. They argue that the TRIPS Agreement has not provided adequate means to prevent patents in developed countries that involve misappropriation of genetic resources and traditional knowledge from developing countries, and that a solution needs to be found through improving the TRIPS Agreement. Campaigning organisations[115] have expressed support for the African Group proposal calling for recognition by the WTO of traditional knowledge and rights of local communities. They argue that it does not amount to giving more power to WTO and expanding the TRIPS agenda but rather it is the most effective means to limit the scope of patents and the scope of WTO jurisdiction over knowledge and biodiversity [116].

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112 The protection of traditional knowledge and folklore — Summary of issues raised and points made, WTO Secretariat, IP/C/W/370, of 8 August 2002.

113 IP/C/W/347/Add.1 or WT/CTE/W/210, of 10 June 2002.

114 Taking forward the review of Article 27.3(b) of the TRIPS Agreement, Joint communication from the African Group, IP/C/W/404, of 26 June 2003.

115 GRAIN, Campaign to Demand Adoption of African Group s Proposal on Traditional Knowledge at the WTO Cancun Ministerial, 20 June 2003. See http://www.grain.org

116 Id.

- Switzerland[117] welcomed the mandate given to the TRIPS Council by paragraph 19 of the Doha Declaration to examine the issue of traditional knowledge. However, they think that WIPO s Intergovernmental Committee (see above) is the primary international forum to deal with the intellectual property-related issues of the protection of traditional knowledge . Switzerland considers that it is necessary to start by establishing a working definition of the concept of traditional knowledge and by determining the objectives of its protection.

- The European Union[118] has indicated that the TRIPS Council is not the right place to negotiate a protection regime for a complex new subject matter like traditional knowledge . Their position is that the WTO should build on the work undertaken by WIPO s Intergovernmental Committee and, depending on the outcome of that process, an assessment should take place to decide whether the issue needs to be taken up by the TRIPS Council.

- Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela[119]: Their joint submission argues for the insertion of a provision in the TRIPS Agreement mandating patent applicants for inventions that use genetic resources and traditional knowledge to disclose the source of origin of genetic resources and traditional knowledge, as well as to provide evidence they the necessary prior informed consent has been obtained, and of compliance with national rules on benefit-sharing. These countries consider that such provisions are critical to ensure that the TRIPS Agreement and the CBD are implemented in a mutually supportive manner.

An interesting initiative has been the formation in February 2002 of the Group of Like-minded Megadiverse Countries , which include Bolivia, Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela. Their objective is spelt out in the Cancún Declaration, which states that these megadiverse countries representing nearly 70 per cent of the planet s biological diversity are concerned about the limitations of various international instruments to protect effectively the legitimate interests of the countries of origin of biodiversity [120]. These group of biodiversity-rich and influential developing countries were keen to set up a mechanism for consultation and co-operation to promote their common interests and priorities regarding biodiversity protection and sustainable use. The Megadiverse Group was instrumental in achieving the WSSD mandate for an international regime on benefit-sharing and,

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117 Article 27.3(b), the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge, Communication from Switzerland, IP/C/W/400, of 28 May 2003.

118 Review of Article 27.3(b) of the TRIPS Agreement, and the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, A communication from the European Communities and their Member States, IP/C/W/383, of 17 October 2002 (and WT/CTE/W/223, of 14 February 2003).

119 The relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge, IP/C/W/403, of 24 June 2003.

120 Cancún Declaration of the Like-minded Megadiverse Countries, 18 February 2002, paragraph 1(h). See at http://www.megadiverse.org/armado_ingles/PDF/three/three1.pdf

in November 2002[121], the Group stressed their commitment to promote those international negotiations on access and benefit-sharing, scheduled to begin in February 2005.

As developing countries hope that the current round of international trade negotiations in the WTO will include biodiversity-related issues of access to genetic resources, benefit sharing and the protection of traditional knowledge, the positions are getting more and more polarised and also changing, with a major shift in the African Group from their long-held position that these issues should be discussed in the CBD framework and not in the WTO, to argue for the inclusion of traditional knowledge as part of the TRIPS Agreement, while they continue to support that TRIPS should ban all patenting of life forms.

4.3.2 Positions on the relationship between TRIPS and the CBD:

The African Group and other developing countries maintain their opposition to the patenting of life forms. African countries propose[122] that Article 27(3)(b) of the TRIPS Agreement be revised to prohibit patents on plans, animals, micro-organisms, essentially biological processes for the production of plants or animals, and non-biological and microbiological processes for the production of plants or animals. The minimum change they require would be the clarification that paragraph (3)(b) does not in any manner restrict the rights of Members to resort to the exception in paragraph 27(2) , which is the exception on grounds of ordre public or morality . In the field of genetic resources and traditional knowledge, the African Group proposes that the TRIPS Agreement be modified to require patent applicants to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin [123].

Industrialised countries have positioned themselves at different levels of opposition to the recommendations of developing countries outlined above, especially on the relationship between the CBD and the TRIPS Agreement. The US[124] argues that the purposes of the CBD and TRIPS Agreement are widely disparate and that most of their provisions are unrelated in any way so they consider that there is no need to amend the provisions of either agreement to accommodate the implementation of the other . The US, not Party to the CBD, is also opposed to requiring that patent applicants identify the source of any genetic material or traditional knowledge used in developing their inventions, which they describe as a legal and administrative nightmare [125]. They consider that to ensure a shar-

121 Cusco Declaration on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights of Like-minded Megadiverse Countries, 29 November 2002. See at http://www.megadiverse.org

122 Taking forward the review of Article 27.3(b) of the TRIPS Agreement, Joint Communication from the African Group to the TRIPS Council, IP/C/W/404, of 26 June 2003.

123 Id, at p.6.

124 Review of the provisions of Article 27.3(b) — Further views of the United States, Communication from the United States, IP/C/W/209, of 3 October 2000.

ing of the benefits derived from accessing genetic resources, obligations must arise at the beginning of the process, not at the point of commercialisation [126]. More recently, the US has argued that the provisions of Articles 8(j), 15, 16 and 19 of the CBD are mutually supportive of the TRIPS Agreement and therefore not conflicting [127].

Switzerland also supports the view that the TRIPS Agreement and the CBD can and should be implemented without conflict and so there is no need to modify either of these agreements[128]. But Switzerland has gone further and put forward several proposals to the WTO s Committee on Trade and Environment that would lead to the adoption by WTO members of an interpretative decision to clarify the TRIPS-CBD relationship. In addition, Switzerland s position disagrees with the US position on the use of the IPR system to ensure compliance with regulations on access to genetic resources and benefit-sharing. Switzerland proposes to enable national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. To achieve this, Switzerland s proposal includes amending the Regulations under the Patent Cooperation Treaty[129].

The EU submitted its position[130] on the relationship between TRIPS and the CBD together with its views on the review of Article 27(3)(b) of the TRIPS Agreement. The EU position is that there is no need to amend Article 27(3)(b) and that there is no legal conflict between the CBD and the TRIPS Agreement, which should be read in a mutually supportive way. The EU agrees to discuss the introduction of a system that would allow to keep track of patent applications related to genetic resources, but they consider that the information to be provided by patent applicants should be limited to the geographic origin of the genetic resources or traditional knowledge used in the invention, without being made into an additional formal or substantial patentability criterion [131]. The EU and other industrialised countries, such as Switzerland, Canada and the US, argue that WIPO, rather than the TRIPS Council, is the appropriate forum to deal with issues related to IPRs and access to genetic resources, benefit sharing and traditional knowledge.

In 2002, a group of developing countries submitted their joint opinion on the CBD-TRIPS relationship and the protection of traditional knowledge to the TRIPS Council. Their main arguments were as follows[132]:

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125 Id, at p.5.

126 Id, at p.6.

127 Communication from the United States to the TRIPS Council, IP/C/W/257, of 13 June 2001.

128 Article 27.3(b), the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge , Communication from Switzerland, IP/C/W/400, of 28 May 2003.

129 Id, at pp.6-7.

130 See n.118.

131 Id.

132 The relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge , Communication from Brazil on behalf of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe. IP/C/W/356, of 24 June 2002.

- The TRIPS Agreement and the CBD should be mutually supportive and promote the sustainable use of resources so modifications to the TRIPS Agreement are necessary to ensure that it will not run counter to the objectives of the CBD;
- While the CBD recognizes countries sovereign rights over their biological resources, the TRIPS Agreement allows WTO Members to provide patents over biological resources — the TRIPS Agreement does not prevent bio-piracy activities where patent rights can be claimed in one country over genetic resources that are under the sovereignty of another country;
- The TRIPS Agreement contains no provisions ensuring the prior informed consent of the owners of the biological resources used in the invention. It has no provisions allowing a Member s claim to enforce its national regimes for fair and equitable sharing of benefits from the patenting of its own genetic resources in another country. The TRIPS Agreement should be amended to require that an applicant for a patent relating to biological materials or to traditional knowledge provides:

(i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
(ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and
(iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.

These countries argued that failure to provide a solution to ensure a mutually supportive relationship between the TRIPS Agreement and the CBD may be detrimental to the objectives of both instruments. They claim that to avoid conflicts in the implementation of TRIPS, it is necessary to amend it to accommodate some essential elements of the CBD — in the framework of ongoing negotiations under the Doha Development Agenda.

Using the same arguments, a similar group of countries made a further submission[133] to the TRIPS Council stressing the need to amend the TRIPS Agreement by inserting a provision that mandates patent applicants for inventions that use biodiversity and/or traditional knowledge, to disclose the source of origin of those resources and knowledge, and provide evidence that they have obtained the PIC and complied with national laws on benefit sharing.

More recently, in March 2004, the same group of countries has submitted a checklist of issues to the TRIPS Council[134]. The objective of the checklist is to facilitate more

133 See n. 119.

134 The relationship between the TRIPS Agreement and the Convention on Biological Diversity, submission from Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela (Bolivia subsequently adhered to it). IP/C/W/420, of 2 March 2004.

focused, structured and result-oriented discussions, as these countries report that more than 25 communications and papers on the relationship between the TRIPS Agreement and the CBD have been submitted to the TRIPS Council. The main issue highlighted by this group of developing countries is the challenge to determine the measures that need to be taken within the framework of the TRIPS Agreement to prevent misappropriation of resources and knowledge, and to support the objectives and implementation of the CBD. At its latest meeting, in September 2004, the TRIPS Council considered a proposal by a group of countries[135] to advance discussions on the relationship between the TRIPS Agreement, biodiversity issues and traditional knowledge, but WTO members remained locked in their positions, so no substantive progress was made[136].

Relevant recommendations to developing countries from the UK s independent Commission on Intellectual Property Rights, in relation to patents and biodiversity, the review of the TRIPS Agreement, and the protection of traditional knowledge, are listed below[137]:

- The review of the relevant provisions in TRIPS which is currently taking place in the TRIPS Council should preserve the right of countries not to grant patents for plants and animals, including genes and genetically modified plants and animals.

- All countries should provide in their legislation for the obligatory disclosure of information in the patent application of the geographical source of genetic resources from which the invention is derived. This requirement should be subject to reasonable exceptions as, for example, where it is genuinely impossible to identify the geographical source of material. Sanctions should be applied only where it can be shown that the patentee has failed to disclose the known source or where he has sought to deliberately mislead about the source. The TRIPS Council should consider this in the light of the review of this issue recommended in the WTO Ministerial Declaration at Doha.

- Consideration should also be given to establishing a system whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information either to the country concerned, or to WIPO. WIPO may act as a depository for patent related information of this nature. Through these measures it will be possible to monitor more closely the use and misuse of genetic resources.

- Developing countries need to identify a strategy for dealing with the risk that further harmonisation of patent laws internationally will lead to standards that do not take account of their interests. Such a strategy might seek a global standard reflecting the

135 Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention , submission from Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela, and Bolivia, to the TRIPS Council (revised document IP/C/W/429/Rev.1, of 27 September 2004).

136 See BRIDGES Trade BioRes, Vol. 4 No. 17, of 23 September 2004

137 See n. 17.

recommendations of this report. It could seek continued flexibility in the standards. Or it could be done by rejection of the process if it appears that the outcome will not be in the interests of developing countries.

The complex web of international institutions, legal frameworks, mandates and positions surrounding two biodiversity elements such as genetic resources and traditional knowledge, of increasing economic and research value, creates a difficult scenario for making progress in the protection of biological diversity and associated traditional knowledge. Increased coherence and co-ordination, at the national and international levels, are needed as many of these global fora are often played against each other or used to trade-off different national interests and priorities.

4.3.3 NGO positions

One of the most active NGOs on issues of genetic resources, traditional knowledge, food safety and IPRs is GRAIN (Genetic Resources Action International). GRAIN supports the proposals from developing countries to review Article 27(3)(b) of the TRIPS Agreement, such as the ban on life patents, and a strong mechanism for disclosing that origin of resources, including detailed information on the provider of the materials or knowledge used, and proof of prior informed consent and benefit-sharing[138]. However, GRAIN argues that even if the proposals from developing countries were accepted in full, they would not solve the problem of bio-piracy , as nothing would guarantee that the indigenous or local communities who own the resources and knowledge receive a fair deal in return if the only proof required is that of government agencies.

GRAIN is also concerned that an agreement on disclosure of origin could be regarded as a capitulation on the request for a ban on life patents, as making disclosure of origin a condition for patenting plants or animals contradicts the fundamental principle of no patents on life for which many NGOs campaign[139]. GRAIN questions the change of position of the African Group on the protection of traditional knowledge, and disagrees with the view that the WTO is the place to look for protection of genetic resources or traditional knowledge given that the WTO mandate is narrowly concerned with the promotion of international free trade.

In addition, a coalition of NGOs[140] has put forward a set of proposals (TRIPS on Trial) for the review of TRIPS Article 27(3)(b), calling on WTO members to agree to the immediate review of this provision, which should be conducted outside the wider WTO negotiations. These NGOs argue that WTO members should:

138 GRAIN Briefing, The TRIPS review at a turning point? July 2003. See at http://www.grain.org

139 Id.

140 ActionAid, Berne Declaration, Switzerland, Centro Debate de Accion y Ambiental, Colombia, Institute for Agriculture and Trade Policy (IATP), Latin American Institute for Legal Service Alternative, MISEREOR, Oxfam International, and Third World Network.

- act on the proposal of the African Group and ban patents on life (plants, animals, micro-organisms and all other living organisms and their parts, as well as the natural processes that produce plants, animals and other living organisms).
- respect the right of developing countries to determine the need for appropriate sui generis laws to protect communities and farmers rights, and promote agricultural diversity;
- ensure that the provisions of Article 27(3)(b) of the TRIPS Agreement are consistent with the CBD provisions on national sovereignty, prior informed consent and benefit-sharing regarding access to genetic resources and traditional knowledge; and
- restrict or ban IPRs on plant genetic resources for food and agriculture, in the interest of long-term food security and to prevent bio-piracy.

This group of NGOs considers that the objectives of technological innovation and technology transfer should place IPRs in the context of the public interest of social and economic welfare. They remind us that TRIPS also acknowledges the right of WTO members to adopt measures for protecting overarching public policy objectives, such as public health and nutrition, and socio-economic and technological development, and to prevent abuse of IPRs and anti-competitive practices, although these fundamental objectives and principles have been ignored by certain developed countries in their interpretation and implementation of TRIPS, which are perpetuating the crisis of legitimacy that TRIPS is already facing. NGOs have made specific demands related to the patenting of life and access to medicines, and they recognise that there is common ground among different campaigns relating to the patenting of life, bio-piracy, food security, and public health and access to affordable medicines, as they share the view that TRIPS represents a significant shift in the balance in IPR protection which is too heavily in favour of private right-holders and against the public interest[141].

Another active NGO in the area of IPRs, biodiversity and biotechnology is the ETC Group on Erosion, Technology and Concentration. The ETC Group has monitored for two decades the role of the private sector on policy developments and has alerted about the power and influence of multi-national corporations on the regulation of biotechnology and the use of IPRs[142]. They have reported that half of the world s 100 largest economic entities are transnational corporations, which have unprecedented power to shape social, economic and trade policies . They argue that corporate hegemony is usurping the role and responsibilities of national governments, threatening democracy and human rights. They consider as a priority the creation of capacity to track, evaluate and accept or reject new technologies and their products, for which they propose an International Convention on the Evaluation of New Technologies[143].

141 Id.

142 ETC Group Communiqué, Oligopoly, Inc. — Concentration in Corporate Power, November/ December 2003. See at http:///www.etcgroup.org

143 Id.

Regarding the private sector, the World Business Council for Sustainable Development (WBCSD), a coalition of 165 international companies united by a shared commitment to sustainable development via the three pillars of economic growth, ecological balance and social progress [144], conducted a stakeholder dialogue in 2001–2002 involving companies, NGOs, legal and political experts, to discuss IPRs and biotechnology issues. The aim was to make companies responsive to criticism raised by NGOs, and the process was designed to expose the business community to the views and concerns of its critics and to explore possible solutions[145]. The summary conclusions of this exercise, perhaps unsurprisingly, do not go beyond stating that participants disagreed over the morality of patents on genes , but they also include confirmation that companies must comply with the CBD and refrain from unauthorised appropriation of traditional knowledge through breach of confidentiality or through filing patents for knowledge that exists as prior art [146]. There was also broad agreement that imposing a global order of IPRs through TRIPS tends to favour developed more than developing countries, and that the acceptance of TRIPS will be seriously jeopardized if developed countries continue to fail to live up to their promises to grant market access [147]. While it is positive that business coalitions such as the WBCSD try to engage with civil society and campaigning organisations on these issues, it seems that their efforts are unconnected to the closed room influence that some large businesses achieve over major public policies and national negotiating positions at international fora.

The impact of civil society on the process of setting IPR standards should be highlighted. After governments and business, NGOs are considered to have become a third force in the global politics of IPRs [148], operating as an analytical resource as well as partners of developing countries. However, these coalitions are mostly issue-specific and considered to be difficult to put together and manage. A crucial aspect is that they do not threaten the dominance of the US and the EU in global IPR policy, especially when they agree on the direction of global IPR regulation[149].

144 See http://www.wbcsd.ch

145 WBCSD, Intellectual Property Rights in Biotechnology and Health Care — Results of a stakeholder dialogue, July 2003.

146 Id.

147 Id.

148 See n.4.

149 Id.

4.4 Plant varieties for food and agriculture: UPOV, TRIPS and the FAO Treaty

Regarding the protection of plant varieties and plant genetic resources for food and agriculture, the applicable international regimes that regulate access to those resources, benefit-sharing and IPRs are those of TRIPS, UPOV and the new FAO International Treaty of 2001, which entered into force on 29 June 2004.

TRIPS Article 27(3)(b) allows exceptions to patents and, in the case of plants, they can be exempted from patentability if they are subject to a sui generis regime. The International Union for the Protection of New Varieties of Plants (UPOV), an intergovernmental organization with headquarters in Geneva (Switzerland), was established by the International Convention for the Protection of New Varieties of Plants[150], whose objective is the protection of new varieties of plants through plant breeders rights (PBRs). The UPOV treaties are considered a sui generis system of protection designed to address the needs and rights of plant breeders. However, the TRIPS Agreement does not specifically mention any IPR agreement regarding plant varieties such as UPOV 1978 and 1991. This circumstance differs from other IPRs such as patents or copyrights, where the TRIPS Agreement requires compliance with previously established standards of IP protection in specific treaties or conventions.

The first UPOV Act was drafted in 1961 by industrialised countries which wished to protect their plant breeders in domestic and international markets. The UPOV convention was later reviewed by the 1972, 1978 and 1991 Acts[151]. UPOV 1991 entered into force in April 1998, and since then UPOV 1978 has been closed to new accessions. UPOV 1991 is considered more favourable to plant breeders and more restrictive for farmers. The UPOV Convention establishes minimum standards such as requiring the breeder s prior authorisation for at least three activities regarding protected varieties: (i) production for commercial purposes; (ii) offering for sale: and (iii) the marketing of the reproductive propagating material of the variety.

Under UPOV 1991, a plant variety must be novel, distinct, stable, and uniform (or homogeneous, in UPOV 1978). The right of breeders both to use protected varieties as an initial source of variation for the creation of new varieties, and to market these varieties without authorisation from the original breeder (the breeders exemption) is upheld in both versions. A key difference in UPOV 1991 is that if a new variety is deemed to be essentially derived from a protected variety, the owner of the protected variety enjoys the same rights over the essentially derived variety as if the two varieties were identical[152]. UPOV 1991 also differs from UPOV 1978 in a number of other important areas:

150 54 countries are currently members of UPOV. See http://www.upov.int

151 The 1991 version entered into force on 24 April 1998. That day the 1978 treaty was closed to new accessions, except for a few countries which had already started that process.

152 See n.14.

- Coverage: UPOV Parties must bring all plant species within the scope of their PBR legislation within 10 years of acceding to the 1991 Act;
- Term of protection: UPOV 1991 requires a minimum of 20 years protection (25 years for trees and vines), while under the 1978 Act the requirement was 15 and 18 years respectively.
- Scope of plant variety rights: unlike the cascade of rights available under the 1991 Act, rights under the 1978 Act extended only as far as the propagating material of a plant breeder s protected variety.
- Right to double protection: UPOV 1991 Act allows a plant variety to be protected both by a PBR and by a patent. UPOV 1978 forbade this.

Concerns have been raised that the UPOV system was designed to accommodate the large-scale commercial agricultural systems in Europe and therefore is unsuitable for most developing countries, due to the implications for small farmers and rural communities. UPOV has also been criticised for promoting the interests of commercial plant breeders in the North rather than the farming communities[153]. The uniformity requirement is said to contribute to genetic erosion and the cost of maintaining UPOV certification is considered beyond the means of most farmers. In addition, the type of protection granted by UPOV s PBRs is an exclusive monopoly right, with certain exemptions for other breeders. This contrasts sharply with the broader goals of collective remuneration and benefit-sharing expressed in the CBD and the FAO Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture[154].

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture recognises the contribution that local and indigenous communities and farmers from all over the world have made towards the conservation and development of plant genetic resources for food and agriculture[155]. This treaty provides some general guidance on the scope of the rights which must be protected, but it leaves total discretion to Parties as to the measures to be adopted in order to protect and promote farmers rights, which are[156]:

- the protection of traditional knowledge relevant for plant genetic resources for food and agriculture;
- the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
- the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

153 South Centre, workshop report, The Patenting of Plants: The Controversial TRIPS Article 27.3 (b), 1998, see http://www.southcentre.org

154 Id.

155 2001 International Treaty on Plant Genetic Resources for Food and Agriculture, Article 9(1).

156 Id, at Article 9(2).

However, the International Treaty does not address the rights of farmers over their own varieties, and the recognition of farmers contribution to the conservation and improvement of plant varieties does not extend to property rights. In this sense, the only rights that are included are those to to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate [157](emphasis added).

The new FAO Treaty represents a substantial step forward for the regulation of plant genetic resources, moving from a non-binding regime to a mandatory system. However, and despite the lengthy international negotiations, not all the crucial issues could be adequately solved in the Treaty text, and so the success of this regime will largely lie in post-agreement developments and further negotiations at the international and national level.

4.4.1 The African Model Law

Africa is the source of many crop varieties. About 70 percent of tropical fodder grasses and 25 percent of legumes cultivated worldwide originate from Africa[158]. The Organisation for African Unity, now the African Union, led a process to assist African countries in protecting their biodiversity and agricultural systems while complying with their CBD- and TRIPS-related obligations. This initiative resulted in the development of the Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources , which was endorsed by the OAU Heads of State in 2000, recommending that it become the basis of all national laws on these issues across Africa.

The main aim of the OAU s Model Law was to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural genetic resources, and knowledge and technologies, in order to maintain and improve their diversity as a means of sustaining all life support systems . Other objectives of the Model Law were to protect and support the rights of local communities over their biological resources, knowledge and technologies; and to promote the supply of good quality seed/planting material to farmers; as well as ensuring that biological resources are utilised in an effective and equitable manner to strengthen food security[159].

In May 2001, the OAU met with WIPO and UPOV to seek comments on the Model Law, which were critical[160]: WIPO argued that the prohibition of patents on life goes against TRIPS Article 27(3)(b), as it requires patents on micro-organisms, and also rejected the inalienability of community rights embedded in the Law. UPOV officials reworked

157 Id, at Article 9(3).

158 Singh H, Emerging Plant Variety Legislations and Their Implications for Developing Countries: Experiences from India and Africa, Paper presented at the Conference TRIPS — Next Agenda for Developing Countries, Shyamprasad Institute for Social Service, Hyderabad, 11–12 October 2002

159 OAU Model Law, Part I — Objectives.

160 See n.158.

more than 30 provisions of the Model Law to make them conform to the UPOV convention[161]. This points towards the desire to limit the sui generis option of Article 27(3)(b) to the UPOV Convention, a treaty promoted by industrialised countries to achieve global harmonisation of IPR laws worldwide based on Western standards as the international level of IPR protection.

4.5 Current trends in IPR policy: the misuse of bilateral free trade agreements

The growing number of developing countries joining UPOV 1991 is partly due to the also fast increasing number of bilateral and regional trade agreements being negotiated by the US, EU, and other industrialised nations, with developing countries. Those bilateral trade treaties often require developing countries to either join UPOV or upgrade from UPOV 1978 to UPOV 1991 even if they are already Parties to the TRIPS Agreement, as in most cases the IPR provisions of these free trade agreements include stricter IPR standards than the minimum levels set by the TRIPS Agreement, which also allows Parties some flexibility, as in the case of plant varieties. This is why these treaties are called TRIPS-plus (or TRIPS +) agreements. Some examples of such bilateral treaties include the 1998 US-Nicaragua agreement; the 2000 US-Jordan treaty and the 2003 Free Trade Agreement between the US and Chile[162].

Equally important is the implications of rising national IPR standards as a result of a particular bilateral trade agreement, as according to WTO rules such IPR protection must be extended to all other WTO members. Bilateral trade agreements are being used (some would say misused) to increase IPR standards beyond TRIPS requirements[163]. This amounts to an active policy by the most powerful global economies to undermine the multilateral trade system while international negotiations under the WTO Doha agenda are not progressing as planned.

But the US is not the only driver in this change of global trade tactics, GRAIN has reported that the EU has forced TRIPS-plus commitments, including IPRs on life forms, in nearly 90 developing countries[164]. GRAIN has defined TRIPS-plus agreements as those going beyond the TRIPS Agreement and, more specifically, as any treaty that contains an obligation to[165]: (i) implement or join the UPOV conventions; (ii) grant patents on plants or animals; (iii) join the Budapest Treaty on the International Recognition of the Deposit of

161 Id.

162 Vivas-Eugui D, Regional and bilateral agreements and a TRIPS-plus world: the Free Trade Area of the Americas (FTAA) , Quaker United Nations Office (QUNO), Ginebra, 2003.

163 Drahos P, BITs and BIPs , Journal of World Intellectual Property Law, 2001.

164 GRAIN, TRIPS-plus must stop: The European Union caught in blatant contradictions, March 2003.

165 GRAIN, TRIPS-plus — How FTAs and other bilateral treaties impose IPRs on life in developing countries, February 2004.

Micro-organisms for the Purposes of Patent Procedure; and (iv) conform with the highest international standards of IPR protection. GRAIN has called on the EU to immediately cease and desist from imposing TRIPS-plus measures on developing countries .

In addition, the Group of the Greens in the European Parliament asked the European Commission about the reasons for upholding the flexibilities of the TRIPS Agreement at the multilateral level while simultaneously making TRIPS-plus demands, such as the accession to UPOV 1991, on developing countries at the bilateral level[166].

Connections can be drawn between TRIPS-plus agreements promoted by US and the EU, and multinational corporations benefiting from IPRs over biotechnology. Considering that some 75 developing countries have made commitments to recognise industrial patens on plants and animals, including GMOs, as a result of bilateral agreements with the US and the EU[167], the market gains for industry are clear, especially when those developing countries have the choice not to accept those high IPR standards under the TRIPS Agreement. The use of bilateral trade negotiations to enhance global IPR standards in exchange for developing countries market access for their products in the North has being actively promoted by the US and the EU in recent years. The bargaining power of developing countries in such small negotiating fora on a one-to-one basis is proving clearly diminished in comparison with the leverage that they can operate in multilateral trade talks by presenting joint positions and through the increased leverage they get from the G-77, regional groups and other alliances.

The growing number and importance of such bilateral trade agreements has resulted in a joint initiative by a group of NGOs which have recently set up a specific website critical of such agreements and providing news, articles and follow-up on this issue[168].

166 The Greens in the European Parliament, press release: EU goes further than WTO on Intellectual Property Rules, 25 March 2003.

167 See n.165.

168 See http://www.bilaterals.org (´a collective effort to share information and stimulate cooperation against bilateral trade and investment agreements that are opening countries to the deepest forms of penetration by transnational corporations´).

5. A way forward?

Having gone through key discussions at the international level on intellectual property rights, biodiversity, traditional knowledge and food safety, it is clear that the international IPR regime is relevant and plays an important role in the conservation and protection of biological diversity, traditional knowledge systems and rural livelihoods at the global level, and especially in the developing world. However, views on that role, its adequacy, effectiveness, and need for change, vary widely among countries, regions, institutions, indigenous peoples, and civil society at large.

The TRIPS Agreement, with its 147 Parties, the CBD with 188, and WIPO with 180 Member States, mean that countries need to make the IPR and biodiversity regimes work together, while making the necessary adjustments or amendments to make that happen. All the international IPR and biodiversity treaties need national legislation and other mechanisms to be implemented and achieve their objectives, both the ones found in the CBD, such as the fair and equitable sharing of benefits arising from the use of genetic resources; the conservation and sustainable use of biological diversity; and the objectives of the TRIPS Agreement: the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations . Parties disagree over the compatibility or otherwise of these regimes and some consider that the objectives or their operationalisation need revising to make them fully compatible. This is the current situation at the international level.

But very little in international law and politics is simple or straightforward. Issues, institutions and people are connected and inter-linked, governments are influenced by economic considerations, industry needs, public opinion, investment flows and trade relations, among other factors. In addition, the international legal infrastructure is heavily complex. Overtime a considerable number of international treaties and conventions have been adopted, amended and further developed, while they interact with an increasing number of regional and bilateral agreements on issues that are inter-connected or just related. Discussions and decisions taken in one forum have implications in others, to a bigger or lesser degree, and countries need to share information and improve coordination to present coherent positions in all fora, which is not always the case, not even among the best resourced industrialised countries.

It is often useful to look back and consider how it all started to help guide us through the way forward. In the early 1990s, the CBD and the WTO were negotiated almost simultaneously but also in a disconnected way: trade experts, lawyers and economists were shaping the future global trade rules, while those concerned with wildlife, the environment, and the preservation of the traditional knowledge of indigenous peoples regarding nature, were negotiating a new international treaty aimed at biodiversity conservation, sustainable use, and fair sharing of benefits derived from genetic resources. However, the TRIPS and CBD regimes have a common feature: they establish a few specific and measurable

obligations but mostly leave flexibility to countries as to how to achieve the set objectives they lay down. TRIPS has minimum standards and allows exceptions on the obligations it sets, while the CBD would need further discussions and incentives over the years to move closer to its objectives, without being able to report much success after its first 10 years as we continue facing the loss and decline of biological diversity.

What has significantly changed in the last 10 years is technological developments and industrial processes that can make further use of natural resources and turn them into commercial products and processes for which there is a growing market in industrialised countries. Those markets and bussinesses are increasingly attracting profits and further investment, while they need IPRs to ensure maximum returns and prevent others from freely using the results of their investment. Add to the equation the increased organisation and influence of groups of developing countries at the international level, and the result is a shift to one-to-one trade negotiations between the biggest economies in the world and individual developing countries, individually or grouped in sub-regions or regions. The result is a further loss of the flexibilities allowed by global rules, as powerful industries in powerful countries are moving faster than the national implementation of TRIPS and CBD, while they try to influence the ongoing international negotiations in line with their needs and objectives.

This is where we currently are and, to look at the way forward we need to firstly consider the priorities and needs of all the relevant actors and elements to assess what the future will bring. Will it be the failure of the Doha mandate? Long and protracted negotiations on an international regime on access to genetic resources and benefit-sharing? A continuous stream of new bilateral free trade agreements with developing coutries incorporating stricter IPR obligations? UPOV achieving global membership?

A more constructive approach in looking ahead is also possible, by pointing to some of the unresolved issues that need to be further addressed and explored[169]: (i) it is not certain that increased availability of IPR protection will automatically lead to greater levels of innovation in society; (ii) we still do not know how far biodiversity is affected by IPRs on seeds, plant varieties and agro-chemicals, but we cannot afford to wait for conclusive proof one way or the other before making decisions on the design of environmentally sound IPRs, including the application of the precautionary principle in the IPR context; and (iii) while patents are clearly unsuitable to protect the rights of traditional knowledge holders, the use of other IPRs may be appropriate in some circumstances.

NGOs and campaigners will also be crucial in shaping of the way forward[170], with proposals for an alternative to UPOV having been suggested by the Indian NGO, Gene Campaign, while groups such as Third World Network, GRAIN, and the Research Founda-

169 Dutfield G, Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties, IUCN and Earthscan Publications Ltd., 2000.

170 See n. 46.

tion for Science, Technology and Ecology have advocated community IPR regimes. In addition, there have been suggestions to recognise and make operational concepts such as traditional resource rights, which encompass intellectual and physical resource and cultural rights.

Developing countries themselves are part of the system but also more numerous in the United Nations than industrialised countries. They are actively submitting proposals in international fora while planning and undertaking measures at the regional and national level. The way forward will be to a large extent dependent on their bargaining power, their priorities, and alliances. The future direction of these policy areas will be the result of the legal and institutional systems set in the past, the current global circumstances, and the interest of governments and politicians, determined to a large extent by the opinion of citizens and the private sector. The final results are uncertain, but decisions taken in the fora analysed in this paper, CBD, WTO, WIPO and FAO, will determine the future of global biodiversity and the survival of traditional knowledge systems from indigenous peoples and local communities.

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CBD COP Decision IV/9, para.16.

CBD: COP Decision VI/24 Part A.

CBD: COP Decision V/26, para. B.1–4

CBD: COP Decisions V/26B, para.4 and VI/24D, para.1.

CBD: COP Decision VI/10F, para.34.

CBD: COP Decision VI/24, para D.10

CBD: COP Decision VI/24C, para.4.

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